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Health-Related Quality of Life and CD4 cells status of Patients receiving Antiretroviral Therapy in Nigeria

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ABSTRACT

Background: The goals of antiretroviral therapy (ART) are to improve patient's health-related quality of life (HRQOL) and restore immunologic function among others.

Objectives: The study evaluated HRQOL and CD4-cells response of HIV-infected patients at months 0 and 6 of receiving ART in Maitama District Hospital Abuja, Nigeria.

Methods: HRQOL of a cohort of 150 HIV-infected patients was evaluated at months 0 and 6 of receiving ART using Medical Outcomes Study Short Form-36 (MOS SF-36) which has 8 domains. These include physical functioning, physically and emotionally related role limitations, social functioning, pain, energy/fatigue, emotional well-being and general health. A paired samples t-test was used to compare the HRQOL scores and CD4 cells count of participants at months 0 and 6. Wilcoxon's signed-ranks test was used to compare HRQOL of male and female participants. At two-tailed test, p value of <0.05 was considered significant.

Results: The mean age (±SD) of the 150 participants at ART initiation was 34.3 ± 8.4 years; 59.3% were females. The mean (±SD) HRQOL of participants increased significantly from 71.9% ± 20.9 at ART initiation to 89.7% ± 10.6 after 6 months of ART ($p<0.05$). The change in all SF-36 domains was statistically significant ($p<0.05$) except for the domains of role limitation due to emotional problems, social functioning and pain. The improvement in the mental component score (MCS) was significant ($p<0.05$) unlike that of the physical component (PCS). The difference in the HRQOL of male and female participants at months 0 and 6 was not significant. The mean CD4 cell count (±SD) increased from 185.7 ±91.0 cells/mm3 at month 0 to 199.0 ±104.7 cells/mm3 after 6months of ART; though this increase was not statistically significant.

Conclusion: There was significant improvement in the mean HRQOL scores of participants which was not associated with significant improvement in the CD4 cells status after six months of ART. The evaluation of HRQOL alongside the clinical and immunological parameters when monitoring treatment outcomes is recommended.

Key words: HIV/AIDS, Antiretroviral therapy, Outcomes, Quality of Life, Nigeria

INTRODUCTION

Quality of life (QOL) is 'an individual's perception of their position in life in the context of the culture and value system in which they live, and in relation to their goals, expectations, standards and concerns'.[1] Factors that have the potential to affect a person's QOL include health, culture, religion, environment, education and finance among others.[2, 5] Health is an important determinant of a person's QOL. Health-related quality of life (HRQOL) is the main concern of health care professionals which is becoming an important health outcome indicator.[3] The impact of HIV infection and its symptoms on the dimensions of quality of life QOL, including physical and emotional well-being, social support systems, and life roles, has emerged as a key issue for persons infected with HIV.[4,5] For example, chronic diarrhoea affects up to 50% of HIV-infected persons[6] and may result in significant deterioration in daily social and other routine activities, and general health status.[5] Socio-demographic factors such as older age, female gender, unemployment, and low income, have been associated with poor HRQOL.[7, 8] Diverse HRQOL assessment tools have been used in persons living with HIV. These include HIV-specific instruments such as World Health Organization Quality of Life Questionnaire for HIV/AIDS (WHOQOL-HIV), HIV-QOL Questionnaire (HIV-QL31), Functional Assessment of HIV Infection (FAHI), HIV/AIDS Quality of Life (HAT-QOL), Multidimensional Quality of Life Questionnaire for HIV/AIDS (MQOL-HIV) and Medical Outcomes Study HIV Health Survey (MOS-HIV) among others. The Medical Outcome Study Short Form-36 (MOS SF - 36)[9] is not HIV-specific. However, its reliability and validity for HIV patients have been supported by several studies.[10-12] The goals of antiretroviral therapy (ART) include the improvement of quality of life (QOL), reduction of HIV-related morbidity and mortality, restore and preserve immunologic function, suppression of the virus and enhancement of survival.[13] The first six months of HAART are critical as clinical and immunological improvement should manifest within this period. These are not always apparent and drug toxicities may emerge. Some patients may fail to respond as expected or may even exhibit clinical deterioration initially.[14] ART has proved efficacious in improving the CD4 cells count of patients over time [15]; however, toxicities of antiretroviral drugs can negatively affect patients' HRQOL.[5] In a study that determined the impacts of HIV infection and use of HAART on QOL in HIV-infected women using the MOS SF-36 form, HIV infection deteriorated the QOL physical health summary score and it remained lower following HAART compared to the score prior to infection. However, HAART enhanced the mental health functioning.[16] In another study that investigated the impact of the first year of HAART on HRQOL using MOS SF-36 form, 27.0% of patients with a normal baseline HRQOL experienced a deterioration of HRQOL while 28.7% of patients with a low baseline HRQOL achieved a normal HRQOL at 12 months of HAART.[17] A significant improvement in HRQOL has also been reported in a cohort of ART-naive patients in studies that compared changes in HRQOL at different time intervals with baseline HRQOL using Medical Outcome Study HIV Health Survey (MOS-HIV) questionnaire.[18, 19] In a study that analyzed HRQOL evolution over 5 years among HAART patients using MOS SF-36 physical (PCS) and mental (MCS) scores, the HRQOL changes occurred in two-phases that were characterized by an initial improvement during the year following HAART initiation and a relative stabilization thereafter.[20] HAART was also found to be associated with short-term improvements of four QOL domains: role functioning, social functioning, pain and perceived health index in a study that assessed effect of HAART on QOL in HIV-infected women using a shortened version of the MOS-HIV.[21]

The HRQOL in patients receiving HAART in industrialized countries have been evaluated in many studies.[16-19] The baseline HRQOL of the individuals from developing nations as Nigeria may not be the same with those from industrialized countries. This difference may be attributed to variations in the economic development and quality of health care between countries. The baseline value may affect the resultant changes in the HRQOL of HIV-infected patients on HAART in different countries. Poor healthcare resources, inadequate infrastructures, stigma and discrimination, socio-economic factors such as poverty, cultural beliefs and ignorance might make access to HIV care and treatment more difficult for HIV-infected patients. These factors may adversely affect the HRQOL. Assessment of HRQOL may assist in monitoring disease progression [22,23] and allow patients to emphasize those areas of their health that are of most concern to them. However, HRQOL is not routinely evaluated when assessing patients' therapeutic outcomes; and it is imperative to evaluate the HRQOL in ART patients alongside clinical/immunological outcomes in this setting. This study evaluated the HRQOL and CD4 cells count of HIV-

infected patients on ART at months 0 and 6 in HIV treatment centre in Nigeria.

METHODS

Research Design

The study design involved a single-group cohort which was defined using predetermined selection criteria and was followed up only after 6 months of ART.

Follow- up HRQOL and CD4 cells were evaluated for participants who reported at the general out-patient pharmacy department of the study site after 6 months of ART for medications refill. Those patients who did not come for their refill appointment after 6 months of ART were not tracked to determine whether they are loss to follow up, death, stopped treatment or transferred out.

Setting

This study was carried out in Maitama District hospital, Abuja, Nigeria, a purposively selected secondary public health care facility. The hospital offers comprehensive HIV care services including ART. HIV positive clients identified at the HIV counselling and testing service points in the hospital are enrolled into HIV care and then followed up. Only those who meet the eligibility criteria for starting ART based on the Nigeria national ART guideline[27] are commenced on treatment. Baseline laboratory assessment is done before ART initiation while follow up laboratory monitoring of CD4 cells count is done 3 months after initiating therapy and thereafter every 6 months for adults. HIV diagnosis and commencement of ART do not usually happen in one day visit. HIV-positive ART-eligible patients are taken through 3 different sessions of adherence counselling and education; and his/her commitment to adhere to ART are sought and obtained before ART initiation. These counselling sessions happen at pre-treatment clinic appointment visits. The ART patients come for a refill of their antiretroviral medications in the general out-patient pharmacy department every two months. There was no protocol in place for the periodic evaluation of the patients' health-related quality of life. In Maitama District Hospital, antiretroviral drugs and a number of drugs for the treatment of opportunistic infections and other related services are fully funded by President Emergency Fund for AIDS Relief (PEPFAR) through United States Agency for International Development (USAID) and are provided at-no-cost to the patients. About 1256 HIV positive patients were receiving ART in this 92 bed-capacity hospital at the time of the study.

Population /Sample

The study sample included a cohort of 150 HIV positive patients, who commenced ART between 1st April, 2009 and 31st July, 2009 based on the predetermined selection criteria.

Selection Criteria

All adult HIV-positive treatment-naïve patients who commenced ART between 1st April, 2009 and 31st July, 2009 were approached to participate, but only individuals who consented were included and followed up in the study. For follow-up HRQOL assessment, only participants who came to refill their antiretroviral medications after 6 months of ART were included.

All HIV-positive patients who were treatment-experienced, and those who were treatment-naïve but less than 15 years of age were excluded. All adults' patients, who did not commence ART between 1st April, 2009 and 31st July, 2009 and those who commenced ART within this period but did not consent to participate were also excluded. For follow-up HRQOL assessment, participants who did not come to refill their antiretroviral medications after 6 months of ART were also excluded.

Sampling Size Calculation

Sample selection was done based on the set inclusion criteria. The sample size (n) was calculated according to the formula described by Yamane and Taro[24] as follows:

$$n = \frac{N}{1 + N(e)^2}$$

Where: n = the sample size; N = Total patients' population that commenced ART between 1st April, 2009 and 31st July, 2009. This is estimated at 160 patients with an average monthly ART enrolment of 40 patients; e = the level of precision (± 5%);

$$n = \frac{160}{1 + 160(0.05)^2}$$

$= 114.3 \approx 114$ patients

The calculated sample size (n) was a total of 114 patients but a total of 150 patients were recruited to accommodate for loss to follow up or defaulters.

Data Collection

The Short Form 36 version II (English) questionnaire was pre-tested for linguistic validation using similar patients' cohort in a different hospital (Wuse General Hospital, Abuja) which has characteristics similar to

the study site. The institutional approval and informed consent from participants were obtained. The questionnaire was self-administered predominantly but the trained research assistants administered to patients who cannot read or write with proper interpretation at months 0 and 6 of receiving ART. In addition participants' CD4 cells count (cells/mm3) and weights (Kg) were collected at months 0 and 6.

The number of items in the 8 dimensions of 36 items SF-36 questionnaire are as follows: 10 items for physical functioning, 4 items for physically related role limitations, 3 items for emotionally related role limitations, 2 items for social functioning, 2 items for pain, 4 items for vitality (Energy/Fatigue), 5 items for emotional well-being, 1 item for health change and 5 items for general health perceptions.

Data Analysis

The data were analyzed using Predictive Analytics SoftWare (PASW) statistics-18. In accordance with the scoring method for SF-36 survey form, each item in the domain of the instrument was transformed into a 0 – 100 scale. The domain scores were computed by taking the average of the raw scores for corresponding items of each domain in a manner that the higher the score, the better the perceived QOL. A paired Student t-test was used to compare the HRQOL-scores, CD4 cells counts and weight (Kg) of participants at months 0 and 6. The correlation coefficients of the participants' CD4 cells counts (cells/mm3) and weights were also determined at months 0 and 6. The HRQOL scores between male and female participants were also compared using Wilcoxon's signed ranks test. The SF-36® physical component score (PCS), mental component scores (MCS) and norm-based scoring (NBS) Calculator[25] was used to determine the participants' PCS and MCS. The norm-based scores are calibrated such that the average score or norm is 50 and the standard deviation (SD) is 10. NBS estimates scores in standard units as deviations from the average (rather than from the extremes). Descriptive statistics such as simple percentages were also used. A two-tailed p- value of 0.05 was considered significant except otherwise stated.

RESULTS

The mean age of the 150 patients (±SD) at ART initiation was 34.3 ± 8.4 years; 59.3% were females; 56.0% were married and living with spouse; 40.0% were self-employed; 52.0% were aged 26-35 years (Table 1).

Table 1: Frequency distribution of the socio-demographic characteristics of participants at months 0 and 6 of ART

Characteristics	Month 0 (n = 150)		Month 6 (n = 118)	
	Frequency	Percentage	Frequency	Percentage
SEX				
Male	61	40.7	47	39.8
Female	89	59.3	71	60.2
AGE				
=15	0	0.0	0	0.0
16-25	16	10.7	12	10.2
26-35	78	52.0	64	54.2
36-45	42	28.0	33	28.0
46-55	12	8.0	8	6.8
56-65	1	0.7	1	0.8
=66	1	0.7	0	0.0
MARITAL STATUS				
Married and living with spouse	84	56.0	65	55.1
Married and not Living with spouse	4	2.7	3	2.5
Single	41	27.3	34	28.8
Divorced	1	0.7	0	0.0
Separated	1	0.7	1	0.8
Widowed	19	12.7	15	12.7
EDUCATIONAL STATUS				
None	7	4.7	3	2.5
Primary	28	187	20	16.9
Secondary	75	50.0	63	53.4
Post Secondary	40	26.7	32	27.1
EMPLOYMENT STATUS				
Employed	54	36.0	42	35.6
Unemployed	32	21.3	24	20.3
Retired	1	0.7	1	0.8
Student	3	2.0	2	1.7
Self-Employed	60	40.0	49	41.5

The mean age of the 118 (78.7%) patients (±SD) that reported after 6 months of ART for medications refill was 33.9 ± 8.2 years. The HRQOL of these 118 (78.7%) patients were evaluated and compared with their corresponding HRQOL at ART initiation. The HRQOL could not be evaluated for 32 (21.4%) recruited participants who failed to refill their antiretroviral drugs after 6 months of ART. The reason for defaulting could not be ascertained. HRQOL of HIV-positive patients on HAART improved after 6 months of therapy (Table 2).

Table 2: SF-36 domain scores of the participants measured at months 0 and 6 of ART.

Domain	Mean scores (± SD), N =118 Month 0	Month 6	p-value
Physical functioning (PF)	74.5 ± 33.9	92.5 ± 13.1	0.000
Role limitation due to physical health (RF)	79.4 ± 30.6	92.7 ± 14.5	0.000
Role limitation due to emotional problems (RE)	76.4 ± 28.6	76.5 ± 26.8	0.974
Energy/fatigue or Vitality (VT)	68.9 ± 22.5	91.6 ± 9.8	0.000
Emotional well-being / Mental Health (MH)	69.8 ± 21.5	89.0 ± 12.4	0.000
Social functioning (SF)	78.3 ± 25.4	75.5 ± 24.4	0.170
Bodily Pain (BP)	74.4 ± 26.5	74.1 ± 26.6	0.890
General health (GH)	62.3 ± 23.2	86.3 ± 14.3	0.000
Health change	55.3 ± 26.7	77.1 ± 28.0	0.000
Mean HRQOL	71.9 ± 20.9	89.7 ± 10.6	0.000

Mean HRQOL

HRQOL = Health-related Quality of life, SD =Standard Deviation

The number of patients with mean HRQOL < 50 dropped from 20 (17.0%) at month 0 to 2 (1.7%) at month 6; while those with mean HRQOL > 90 increased from 26 (22.0%) at month 0 to 76 (64.4%) at month 6. The improvement in most of the domains of SF-36 was statistically significant ($p < 0.05$) except in the domains of role limitation due to emotional problems, social functioning and bodily pain ($p > 0.05$).There was no statistically significant difference between male and female participants in the HRQOL scores across the SF-36 domains at months 0 and 6 ($p > 0.05$), except at month 0 in the domain of emotional well-being (Table 3). However, the numbers of male and female participants with mean HRQOL < 50 decreased from 10 (16.4%) and 15 (16.9%) to 0 (0%) and 2 (2.8%) respectively. Conversely, the number of male and female participants with mean HRQOL > 90 increased from 15 (24.6%) and 14 (15.7%) to 33 (70.2%) and 47 (66.2%) respectively.

Table 3: Comparison of the SF-36 domain scores of male and female participants at months 0 and 6 of ART

	Mean scores (± SD), Month 0; n = 150			Mean scores (± SD), Month 6; n = 118		
Domain	Male, N = 61	Female, N = 89	P – value	Male, N = 47	Female N = 71	P – value
Physical functioning (PF)	78.0 ± 30.7	69.8 ± 33.8	0.139	96.7 ± 5.8	91.9 ± 13.3	0.652
Role limitation due to physical health (RF)	76.7 ± 29.5	78.5 ± 30.7	0.631	94.0 ± 9.3	90.8 ± 18.1	0.977
Role limitation due to emotional problems (RE)	80.5 ± 25.7	73.1 ± 28.5	0.115	92.7 ± 12.8	91.7 ± 16.6	0.527
Energy/fatigue or Vitality (VT)	66.6 ± 21.4	69.8 ± 21.3	0.425	92.3 ± 7.9	90.7 ± 11.2	0.826
Emotional well-being / Mental Health (MH)	74.4 ± 19.3	66.5 ± 21.9	0.043	92.3 ± 11.1	89.1 ± 11.7	0.197
Social functioning (SF)	78.3 ± 25.7	75.6 ± 26.2	0.861	97.4 ± 10.4	89.7 ± 19.3	0.134
Pain (BP)	73.2 ± 25.9	77.3 ± 27.2	0.690	93.1 ± 13.2	89.6 ± 20.0	0.526
General health (GH)	61.8 ± 22.9	62.3 ± 22.3	0.840	86.9 ± 13.9	86.2 ± 14.2	0.774
Health change	56.2 ± 28.7	55.6 ± 25.5	0.509	84.4 ± 23.1	71.1 ± 33.7	0.463
Mean HRQOL	73.2 ± 18.9	69.9 ± 20.9	0.417	93.1 ± 6.4	89.6 ± 11.3	0.587

HRQOL = Health-related Quality of life, SD = Standard Deviation

Using the norm-based scoring (NBS) with a mean of 50 and standard deviation (SD) of 10, the physical component score (PCS) of the participants increased from 49.6 at ART initiation to 54.7 after 6 months of ART, though not significant ($p > 0.05$).The mental component score (MCS) increased significantly ($p <$

0.05) from 48.9 at ART initiation to 54.1 after 6 months of ART (Figure 1).

The male participants had a PCS increase from 48.8 at ART initiation to 56.8 after 6 months of ART; while their MCS increased from 50.3 at ART initiation to 58.6 after 6 months of ART. The female participants had a PCS increase from 49.7 at ART initiation to 55.6 after 6 months of ART; while their MCS increased from 47.7 at ART initiation to 57.2 after 6 months of ART (Figures 2 and 3). The increment in the PCS for both male and female participants after 6 months of ART were not statistically significant (p = 0.095), whereas the increase in the MCS was found to be statistically significant (p = 0.043).

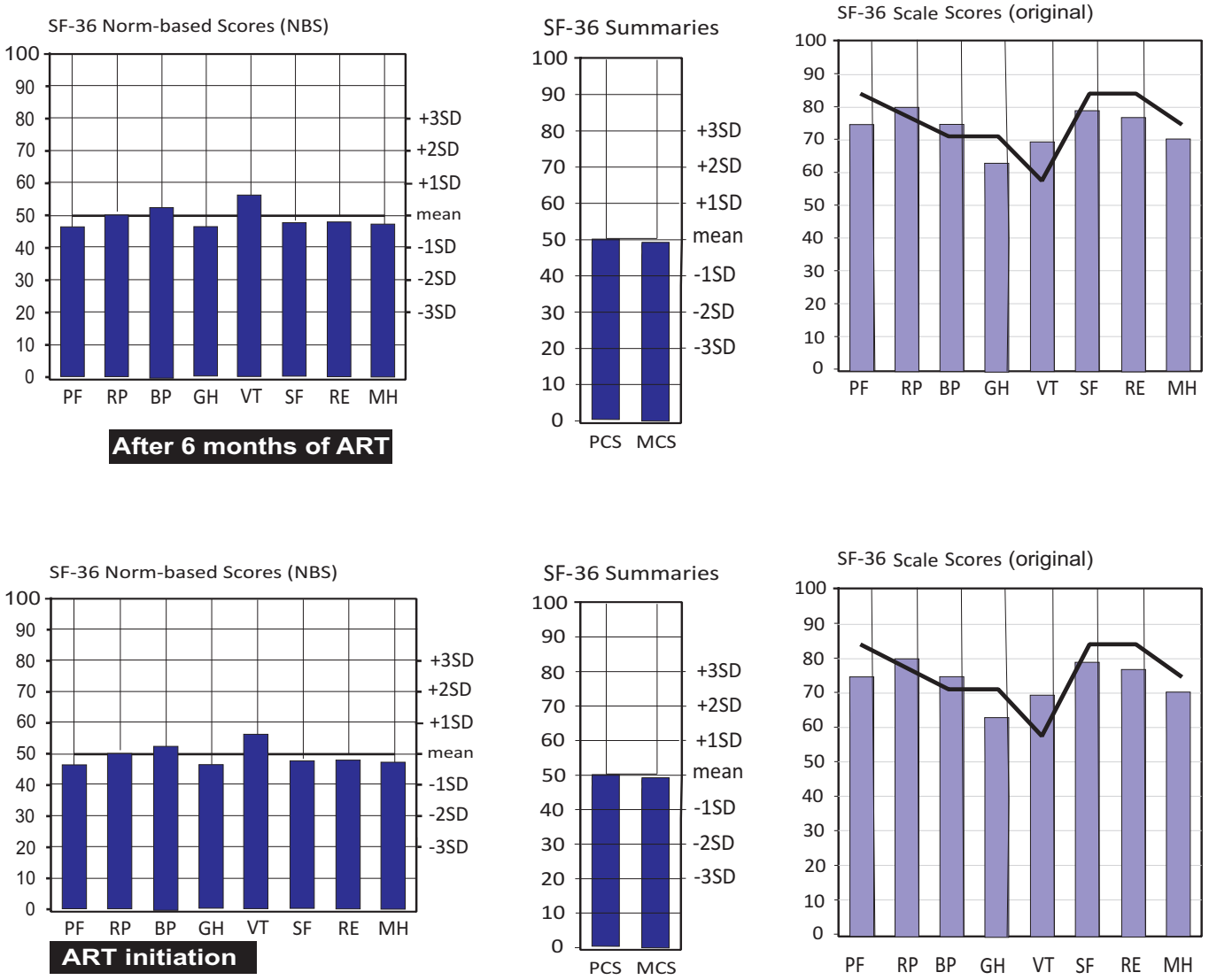

Figure 1: Comparison of SF-36 domain scores, physical component score (PCS) and the mental component score (MCS) of participants at months 0 and 6 of ART

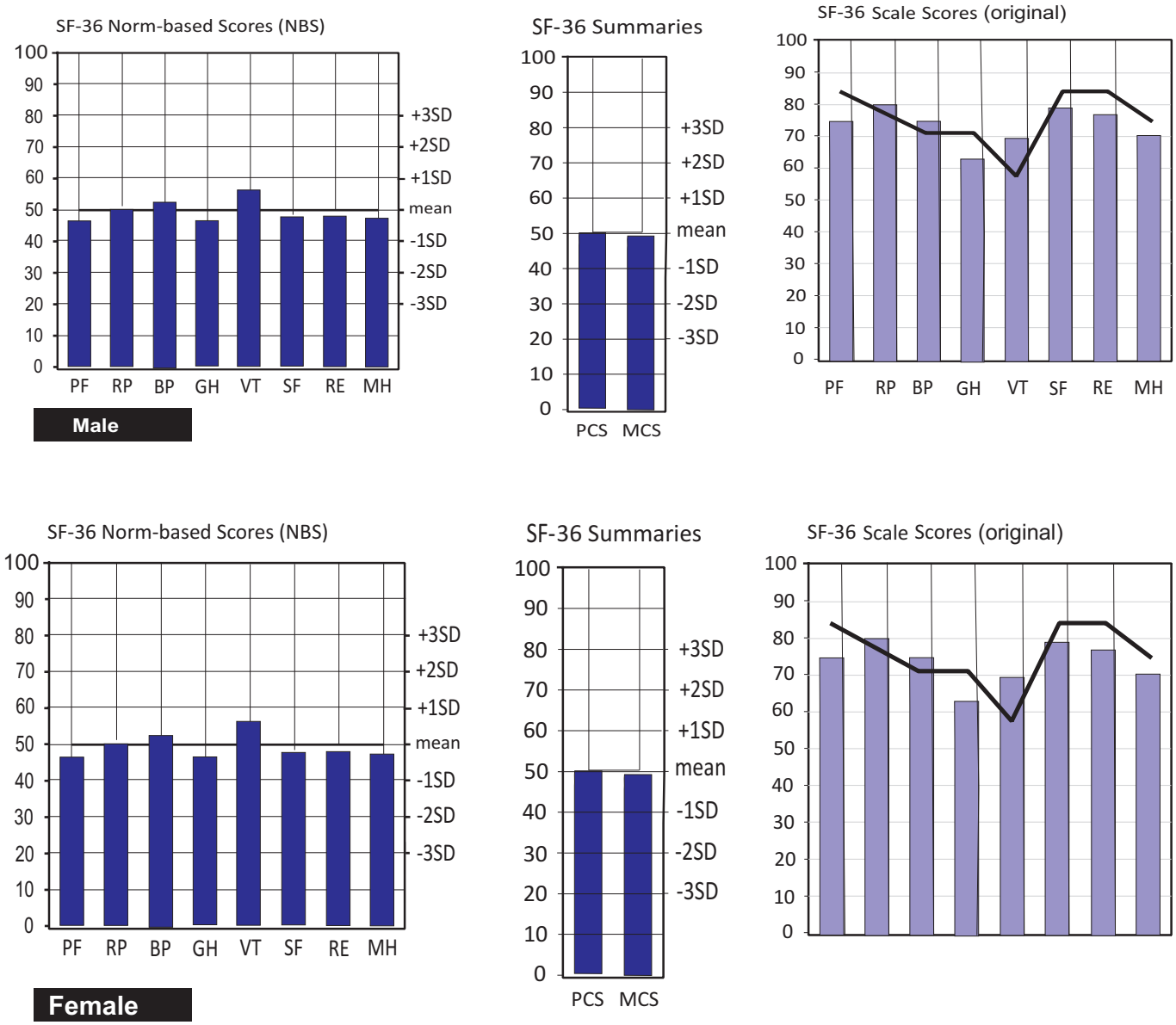

Figure 2: Comparison of SF-36 domain scores, physical component score (PCS) and the mental componentscore (MCS) of participants by gender at ART initiation

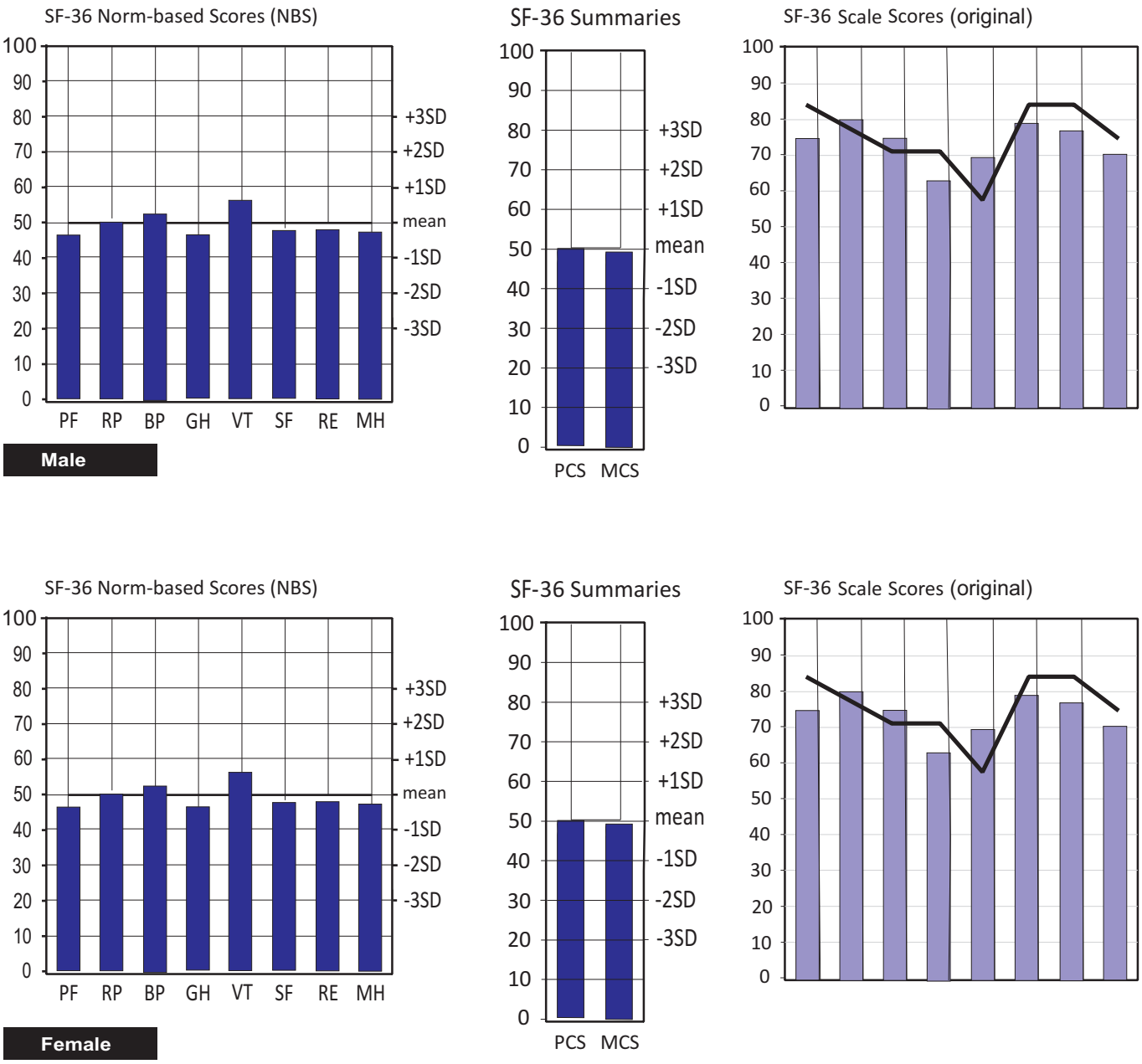

Figure 3: Comparison of SF-36 domain scores, physical component score (PCS) and the mental component score (MCS) of participants by gender after 6 months of ART

The mean CD4 cell count (±SD) increased slightly though not significant statistically (p=0.332) from 185.7±91.0 cells/mm^3 at month 0 to 199.0 ± 104.7 cells/mm^3 after 6 months of ART. However there was a significant positive (though weak) correlation of the participants' mean CD4 cells counts at months 0 and 6 (correlation coefficient = 0.311, p = 0.008). The mean participants weight (Kg) (±SD) of 60.1 ± 11.8 at baseline increased slightly to 63.6 ± 23.8 after 6 months of ART, though not significant (p=0.301). There was a negative correlation of participants' weights at months 0 and 6 which was not statistically significant (correlation coefficient = -0.174, p = 0.144).

DISCUSSION

The HRQOL of HIV-infected patients on HAART improved significantly after 6 months of therapy in this study. This significant improvement was not associated with significant improvement in the CD4 cells status after six months of ART. This result is consistent with the previous studies that reported improvement of the HRQOL in a cohort of ART-naive patients at different time intervals following HAART.[18, 19] Specifically, the study findings showed a significant improvement in HRQOL scores of the participants after 6 months of ART in all domains of the MOS SF-36 except in the domains of role limitation due to emotional problems, social functioning and bodily pain. This exception is inconsistent with previous study by Liu et al[21] that reported short-term improvements of four QOL domains that included role functioning, social functioning and pain in HIV-infected women that use HAART.

HAART enhanced both the physical health summary score (PCS) and the mental health functioning (MCS) of the participants after 6 months of therapy in this study. This is consistent with the earlier reports that the MCS was enhanced following HAART. [16, 20] Liu et al[16] reported that the physical health summary score (PCS) following HAART remained lower than that prior to infection. This may support the insignificant improvement in the PCS of the participants following HAART reported in this study; although the PCS of the participants prior to HIV infection was not determined for a better comparison. In addition, Protopopescu et al[20] also reported an initial improvement in both the physical (PCS) and mental (MCS) scores during the year following HAART initiation and a relative stabilization thereafter.[20]

The study findings also showed no difference in the HRQOL scores in all the SF-36 domains between male and female participants at months 0 and 6. This finding contradicts previous reports in ART patients that female gender was associated with poorer overall HRQOL compared to the male gender.[7, 8] Another study in Nigeria reported a higher HRQOL score in women than men in virtually all domains.[28]

However, at ART initiation, the study reported that HRQOL score in the domain of emotional well-being for male and female gender differs significantly with a lower value for the female participants. The association of HRQOL with gender may need to be further evaluated in a controlled setting following these inconsistent research findings.

As expected, there was clinical and immunological improvement within the first six months of ART.[14] The study reported an improvement in the CD4 cells status of the participants after 6 months of ART which was not statistically significant contrary to earlier reports.[15, 26] Strict adherence to the national guideline for HIV/AIDS treatment and care in Nigeria should be ensured. This guideline prescribes that CD4 cell status of HIV-infected patients on ART be repeated every 6 months[27] for early detection of immunologic failure. In this study, improved HRQOL was not associated with significant improvement in CD4 cell status after 6 months of ART. Therefore, CD4 cell status should be monitored as prescribed in the treatment guideline[27] alongside HRQOL when assessing progress towards the attainment of the goals of ART in patients.[13] Previous studies in Nigeria have evaluated HRQOL of HIV/AIDS patients when they have already commenced HAART, and did not compare HRQOL before and after commencing HAART.[28-30] This study evaluated the HRQOL of HIV/AIDS patients before and after commencing HAART.

Limitations of the study include probable poor/inaccurate recall of information and false response on health status by patients particularly due to inherent overwhelming emotional disturbances of the disease in question. The inability of the researchers to follow up and evaluate the HRQOL of the 32 participants recruited at baseline but defaulted to refill their antiretroviral medications after 6 months of ART may lead to overrating of the overall HRQOL scores. ART services were provided at no cost to patients. This may over-estimate the HRQOL of patients in this setting compared to other hospitals where patients have to pay for ART services including antiretroviral drugs out-of-pocket. The medication adherence status of study participants was not determined; and is one of the determinants of CD4 cells response in patients on ART. Limitations of the study include probable poor/inaccurate recall of

information and false response on health status by patients particularly due to inherent overwhelming emotional disturbances of the disease in question. The inability of the researchers to follow up and evaluate the HRQOL of the 32 participants recruited at baseline but defaulted to refill their antiretroviral medications after 6 months of ART may lead to overrating of the overall HRQOL scores.

CONCLUSION

There was significant improvement in the mean HRQOL scores of participants which was not associated with significant improvement in the CD4 cells status after six months of ART. The evaluation of HRQOL alongside the clinical and immunological parameters when monitoring treatment outcomes is recommended.

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