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PHARMACOTHERAPEUTIC STUDY OF ANTIRETROVIRAL THERAPY FOR HIV/ AIDS PATIENTS AT THE FEDERAL MEDICAL CENTRE, OWO, ONDO STATE, NIGERIA

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PHARMACOTHERAPEUTIC STUDY OF ANTIRETROVIRAL THERAPY FOR HIV/AIDS PATIENTS AT THE FEDERAL MEDICAL CENTRE, OWO, ONDO STATE, NIGERIA

ABSTRACT

A 6-12 months retrospective study is made of HAART utilization in cases of HIV/AIDS patients at Federal Medical Centre, Owo, Nigeria. The objective to evaluate the rational pharmacotherapeutic approach to the management of the retroviral disease. Sixty two (62) antiretroviral drug-naïve HIV/AIDS patients, which comprise of (19) 30.65% males with a mean age of 37.15 ± 8.55 years and (43) 69.35% females with a mean age of 35.68 ± 9.75 years case files are reviewed. The data used for this study was extracted from the clinical records of the Hospital. Sixty six percent of the patients are at World Health Organization (WHO) clinical stage III or IV of the HIV disease at initiation of HAART and 35.70% of patients have baseline CD4 cell count ≤ 50 cells/ μ L. Stavudine/Lamivudine/Nevirapine is used as HAART first line regimen in 87.10% of the patients while 12.90% are prescribed Stavudine/Lamivudine/Efavirenz due to underlying TB infection. Three (3) patients switched their initial regimen while a patient had her regimen discontinued because of drug adverse effects. Evaluation of 35 patients for therapeutic response after a mean period of 9.07 months shows that, in 82.86% of patients, mean CD4 cell count increased from 96.70 ± 67.90 cells/ μ L (median 104 cells/ μ L) at baseline to 267.60 ± 141 cells/ μ L (median 267 cells/ μ L). After a mean period of 9.07 months of HAART, there is a significant difference in the change in CD4 count among male and female patients there is no significant correlation between age and change in patients' CD4 count and within female patients but there is a significant positive correlation between age and change in CD4 count within male patients. It is therefore concluded that rational use of HAART in patients with retroviral disease will lead to significant improvement in most patients' immunological status and invariably quality of life.

Keywords: *Pharmacotherapeutics, HAART, HIV/AIDS, CD4 Count*

INTRODUCTION

Acquired Immune Deficiency Syndrome or Acquired Immunodeficiency Syndrome (AIDS) is a disease of the human immune system caused by the human immunodeficiency virus (HIV) (Weiss, 1993; Sepkowitz, 2001). HIV causes AIDS by depleting CD4 T helper lymphocyte. This weakens the immune system and allows opportunistic infections. T lymphocytes are essential to the immune response and without them; the body cannot fight infections or kill cancerous cells.

The CD4 count serves as the major clinical indicator of immunodeficiency in patients who have HIV infection. It is the most important factor in deciding whether to initiate antiretroviral therapy and opportunistic infection prophylaxis, and it is the strongest predictor of subsequent disease progression and survival according to clinical trials and cohort studies (Mellors *et al*, 1997; Egger *et al*, 2002).

Although AIDS was discovered in 1981 and HIV identified in 1983, it was not until 1985 that the first two HIV cases were identified in Nigeria and were reported at an international

AIDS Conference in 1986 (Adeyi *et al*, 2006). By the end of 2008, the United Nations Joint Programme on HIV/AIDS (UNAIDS) report on Nigeria estimates that around 3.1 percent of adults between ages 15-49 are living with HIV/AIDS (UNAIDS, 2008).

The initial strategy of health experts as regards combating the HIV/AIDS scourge was to focus on reducing the incidence of opportunistic infections that were shown to cause high morbidity and mortality rather than inhibiting the growth of the virus (Fee & Krieger, 1993). However, further studies on the pathogenesis of the disease as well as genetic basis of resistance yielded positive result in 1987 with the registration of zidovudine as the first antiretroviral agent by United States Food and Drug Administration (FDA) (Young, 1988). Since that time, studies into the area of HIV therapeutics has been growing (Burton, 2006). Antiretroviral drugs which are used for the treatment of HIV infection, essentially act by blocking the action of enzymes that are important for replication and functioning of the HIV (Palmisano & Vella, 2011).

The primary goals driving the decision to initiate antiretroviral therapy are to reduce HIV-related morbidity and prolong survival, improve quality of life, restore and preserve immunologic function, maximally and durably suppress viral load and prevent vertical HIV transmission (DHHS Panel on Antiretroviral Guidelines, 2008).

In resource limited setting, initiation of antiretroviral therapy in adults and adolescents is dependent on WHO clinical staging and CD4 count (WHO, 1990). Thus:

The WHO staging system of HIV/AIDS is as follows;

- Stage I: HIV Infection is asymptomatic, generalized lymphadenopathy.
- Stage ii: Weight loss less than 10% of bodyweight, fungal nail infection, herpes zoster, recurrent upper respiratory tract infections (URTIs)
- Stage iii: Weight Loss greater than 10%, unexplained chronic diarrhoea for longer than one month or fever, oral candidiasis/hairy leukoplakia, pulmonary TB, severe bacterial infections.
- Stage IV: AIDS defining illness: e.g. HIV wasting syndrome, PCP, brain toxoplasmosis', candida oesophagitis, extra- pulmonary TB, CMV retinitis, Kaposi Sarcoma, non – Hodgkin's lymphoma. Performance score 4: bedridden greater than 50% of the day during the last month.

Nigeria's national guideline endorses the WHO recommendations for initiating antiretroviral therapy (ART) (FMoHN, 2005).

ART should be initiated in the following categories of patients.

If CD4 testing is available:

- WHO stage IV disease irrespective of CD4 cell count;

- WHO stage III disease with CD4 count $<350/\text{mm}^3$;
- WHO stage I or II disease with CD4 cell count $<200/\text{mm}^3$.

(Note: CD4 cell count $<200/\text{mm}^3$ is believed to be associated with a state of immunosuppression)

If CD4 testing is unavailable,

- WHO stage IV disease irrespective of total lymphocyte count (TLC).
- WHO stage III disease irrespective of TLC.
- WHO stage II disease with a TLC $\leq 1200/\text{mm}^3$

In parallel with the discovery of ARVs has been a rapid evolution of different strategies for optimizing their use (Detel *et al*, 1998). Current treatment for HIV infection consists of HAART. This has been highly beneficial to many HIV-infected individuals since its introduction in 1996 when the protease inhibitor-based HAART initially became available (Beck *et al*, 2004; Murphy *et al*, 2001). Current optimal HAART options consist of combinations (or “cocktails”) consisting of at least three drugs belonging to at least two types or “classes” of antiretroviral agents (DHHS Panel on Antiretroviral Guidelines, 2008). Typical regimens consist of two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) plus either a Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs) or a Protease Inhibitor (PIs) (DHHS Panel on Antiretroviral Guidelines, 2008).

While there are many effective HAART regimens that are used to treat HIV/AIDS, the initial strategy must be based on proven potency, ease of administration, potential drug toxicities, pharmacokinetics, expense and availability.

In Nigeria, the initial choice of dual NRTIs is typically limited to one or two options: stavudine (but currently stavudine is gradually being replaced with tenofovir because of peripheral neuropathy) plus lamivudine or zidovudine plus lamivudine (FMOHN, 2005). Both are said to be effective but their side effect profiles are different. In addition to dual nucleoside reverse transcriptase inhibitors, the third drug of a HAART regimen is a critical choice (Squires *et al*, 2004; Staszewski *et al*, 1999). The most common third drug added to a HAART regimen is a non-nucleoside reverse transcriptase inhibitor, either nevirapine or efavirenz (F van Leth *et al*, 2004). An effective alternative to the non-nucleoside approach is the addition of a protease inhibitor as the third drug in a HAART regimen. PIs based HAART are only used as second line regimens in Nigeria (FMOHN, 2005).

The most effective and practical protease inhibitors to be considered for second line therapy include lopinavir/ritonavir (Kaletra®), indinavir with or without ritonavir, and atazanavir with or without ritonavir (WHO, 2006).

A lot of challenges are being encountered by both patients and care providers in achieving the

goals of therapy. This is due to the fact that HIV/AIDS patients on antiretroviral drugs most often take other medications to treat either opportunistic infections or co morbidities (Antoniou & Lin-in Tseng, 2002). This condition which is referred to as poly pharmacy gives room for potential drug-drug interactions which may modify the expected therapeutic outcomes (Piscitelli & Gallicano, 2001). Another impediment to the realization of full benefits of HAART is patients' non adherence usually resulting from drug adverse effects (O'Brien *et al.*, 2003). Therefore, HAART regimen must be tailored towards individual patient needs if adequate therapeutic response is to be achieved at the end of therapy.

In order to tackle the burden of HIV/AIDS in Nigeria, the Federal government in collaborations with International Donor Agencies started distributing free antiretroviral drugs to patients since 1996 in treatment centres (WHO, UNAIDS and UNICEF, 2008). However little is known about therapeutic endpoints of the drug intervention. The aim of this study therefore, was to determine the appropriateness or otherwise of the current treatment strategies in restoring immunological functions of HIV/AIDS patients among other goals of ART. It is believed that such evaluation would be useful because, it will either reinforced or call for a review of the current strategies.

Materials and Methods

A 6 to 12 month retrospective cohort study of sixty two (62) antiretroviral drug-naive patients who attended Federal Medical Centre, Owo HIV/AIDS clinic between the periods of June 2006 to May 2007 and were offered HAART. The study was approved by Federal Medical Centre Owo, Ethical Review Committee (ERC). To be selected for the study, the patient had to be 13 years of age or older and completely antiretroviral drug-naive at the start of first-line HAART. The patient must have been on HAART for at least 6 months by May 2007. Data for patients were collected retrospectively using patient case files obtained from the Medical Records Department of the health Institution. The files contain information on patient characteristics (e.g. gender, age and weight), tests performed at initiation (Baseline) of ART and during the course of ART (e.g. liver function test (LFT), CD4 cell count, full blood count and drug resistance testing), patient clinical status at the time of initiation of therapy (e.g. WHO clinical stage, concurrent disease and physical assessment), detailed treatment data (e.g. use of antiretrovirals, prophylactic medications against opportunistic infections, concurrent medications, dose frequency, start and stop dates and reasons for treatment change) and adverse effects data. The analysis of the collated data was carried out with the use of both descriptive and quantitative techniques. The descriptive technique involves the use of frequency table and bar chart, while the quantitative technique involved the use of non

parametric statistics Mann-Whitney U-test and Spearman Rank Correlation test (Bangboye, 2006).

RESULTS

Patient categorization based on 2006 WHO clinical staging system

Sixty percent (60%) of the patients studied were at stage III of the WHO clinical stage of retroviral disease (mean CD4 count 87 cells/ μ L), 12.90% at stage I (mean CD4 count 114.88 cells/ μ L), 20.97% at stage II (mean CD4 count 94.92 cells/ μ L) and 6.45% of patients were at stage IV (mean CD4 count 60 cells/ μ L) of the disease (Figure 1).

PATIENT CD4 COUNT AT BASELINE.

All the patients performed baseline CD4 count at the beginning of study, except 6 patients who had total lymphocyte count (TLC) performed due to non-availability of CD4 count determining machine at the time of entry into treatment (The machine was later acquired in November, 2006). The TLC values were <1200 cells/ μ L. The analysis of the patients baseline CD4 cell count showed a range of 4-278 cells/ μ L (mean 92 ± 61 cells/ μ L). About thirty five percent (35.71) of patients had CD4 cell count of ≤ 50 cells/ μ L signifying the stage of severe immunosuppression while $<4\%$ of patients had CD4 cell count of >200 cells/ μ L (Table 1).

HAART REGIMEN USED AS FIRST LINE

Stavudine/Lamivudine/Nevirapine was prescribed as first line regimen in 87.10% of patients while 12.90% had Stavudine/Lamivudine/Efavirenz as first line (Table 2). Other HAART regimen introduced during the course of patients' management were Zidovudine/Lamivudine/Efavirenz and Abacavir/Zidovudine/Lamivudine.

CO-INFECTION AND CO-MORBIDITIES REVIEWED.

Candidiasis (11.30%), malarial (35.48%), pulmonary tuberculosis (13%), upper respiratory tract infections (14.52%) and others (14.52%) were the concurrent infections with HIV while hypertension (19.35%) was the only co-morbidity recorded (Table 3)

CONCOMITANT DRUGS PRESCRIBED

Concomitant drugs prescribed with ARVs, included Antibacterials (Amoxicillin/Clavunilate 16.13%, Ciprofloxacin 12.90% and others 24.19%), Analgesics (paracetamol 17.74%, NSAIDS 8.06%, tramadol 9.68%), Antimalarials (Artesunate/SP 16.13%, chloroquine 8.06%, chloroquine/SP 14.52%, others 21%), chlorphenamine 37.10%, antihypertensives

(Amiloride/HCT 17.74%, captopril 19.35%, methyldopa 11.29%, Nifedipine 9.68%, others 14.52%), metronidazole 19.35%, Bromazepam 11.29%, Fluconazole 9.68%, micronutrients and multivitamins (Heamatinics 100%, Neurovite forte 12.90%, pyridoxine 12.90%) and other drugs 66.13% (Table 4).

DRUG INTERACTIONS BETWEEN CONCURRENT DRUGS AND ARVS

There were the possibilities of drug-drug interactions between the following drugs. Fluconazole/nevirapine (9.68%), rifampicin/nevirapine (1.61%), isoniazid/stavudine (13%) and cotrimoxazole/lamivudine (100%). Table 5.

DOCUMENTED DRUG ADVERSE EFFECTS

The recorded adverse effects include pain (19.35%), diarrhoea (14.52%), weakness/fatigue (4.84%), hallucinations (1.61%), Headache (4.84%), Insomnia (11.29%), itching (20.97%), paraesthesia (9.68%), peripheral neuropathy (3.23%), rash (16.13%), Stevens Johnson syndrome (1.61%) and change in taste perception (1.61%). Table 6.

Change in patients cd4 counts 6-12 months after initiation of HAART.

Out of the 62 patients studied, 21 patients (33.87%) did not repeat CD4 count test 6-12 months after initiation of HAART due to financial incapacitation of patients, 5 patients (8.07%) defaulted while a patient (1.61%) was referred. 35 patients (56.45%) who performed CD4 tests during follow-up visits after a mean period of 9.07 months have their data given in Table 7. The analysis of the CD4 count showed that all except 6 patients numbered 3, 4, 7, 11, 18 and 28 (17.14%), had an increase of >50 cells/ μ L. Mean CD4 cell count of the patients increased from 98.40 ± 66.85 cells/ μ L (median 104 cells/ μ L) at baseline to 267.60 ± 141 cells/ μ L (median 267 cells/ μ L) ($p < 0.01$).

DISCUSSION

Out of sixty two (62) patients studied, 30.65% were males while 69.35% were females giving a male to female ratio of 1 to 2.3. This ratio seems to be in line with findings of a research on HIV/AIDS conducted in Ile-Ife Nigeria which reported a male to female ratio of 1 to 1.4 (Akinola *et al.*, 2004). This is also in agreement with studies that reported that women are more susceptible to HIV-1 infection due to hormonal changes as a result of use of hormonal contraceptives, vaginal microbial ecology and physiology and a higher prevalence of sexually transmitted diseases (Lavreys *et al.*, 2004).

A majority of patients studied in the present work (72.59%) were within the age bracket of

21-40 years with a mean age of 35.20 ± 10.50 years. This finding corroborates with the Federal Ministry of Health year 2001 National HIV/Syphilis sentinel survey (FMoHN, 2001) which reported that over 70% of adults infected with HIV/AIDS in Nigeria falls within the age bracket of 15-34 years. This is the age range that corresponds considerably to years of sexual activity and economic productivity. The implication of this will be a growing number of AIDS orphans and a strong economic burden which could cripple the workforce of the country.

According to the patient categorization based on 2006 WHO clinical staging system, the study showed that 66.14% of the patients belonged to stage III or IV. This implies that majority of the HIV patients did not promptly seek medical treatment until the disease had reached an advanced stage. This might be as a result of either ignorance of availability of free antiretroviral drugs or the fear of social discrimination and isolation which were usually meted to people identified to be living with HIV/AIDS. This finding is similar to Ghana HIV cohort study in which 78% of patients had disease classified as WHO stage III or IV (Collini *et al.*, 2009).

The present work also shows that patients studied had a baseline CD4 count ranging from 4 to 278 cells/ μ L. About thirty five percent (35.71%) of patients had CD4 count of ≤ 50 cells/ μ L signifying the stage of severe immunosuppression. This finding is in line with research conducted in New Delhi, India where CD4 count of < 50 cells/ μ L was seen in 18.6% of patients studied (Guatam *et al.*, 2008). All the patients studied were considered qualified for antiretroviral therapy based on their baseline CD4 count values and WHO clinical stage which is in line with the national guidelines on the use of antiretroviral drugs.

Concerning pharmacotherapy, 87.10% of the patients were prescribed D4T/3TC/NEV as HAART first line regimen while the remaining 12.90% of patients who had concurrent TB infection were prescribed a combination of D4T/3TC/EFV as HAART first line regimen in accordance with the national guidelines. A patient had his regimen (EFV/D4T/3TC) changed to EFV/AZT/3TC due to severe peripheral neuropathy caused by stavudine while another patient was switched from NEV/D4T/3TC to all NRTIs regimen comprising of ABC/AZT/3TC because of resistance and non-availability of protease inhibitor-based second line regimen. However, this combination was inferior virologically to an efavirenz-based regimen and was generally not recommended (Gulick *et al.*, 2004).

As regards concurrent infections and co-morbidity recorded with the retroviral disease only tuberculosis (TB) required special consideration as to the choice of NNRTI to be selected as component of HAART and therefore, efavirenz was given priority over nevirapine because it can be co-administer with rifampicin which is a basic component of anti TB drug regimen

unlike nevirapine which interact significantly with rifampicin which might result in HAART therapeutic failure. However, a patient who had her efavirenz changed to nevirapine three (3) months into therapy because of drug-induced hallucinations defaulted before she could be evaluated.

In the present study, different drugs were prescribed concurrently with ARVs to manage patients. Cotrimoxazole was prescribed for all the patients as prophylaxis against opportunistic infections in conformity with WHO guidelines which recommends the use of cotrimoxazole in all HIV infected patients irrespective of the CD4 count (WHO, 2006). Over 50% of patients who were infected with malaria were treated with combination of antimalarials that contains sulfadoxine/pyrimethamine (SP). This was at variance to WHO recommendations that HIV patients infected with malaria and are already on cotrimoxazole prophylaxis should be treated with antimalarials other than SP because of the problem of cross-resistance (WHO, 2006). This work also revealed that patients with hypertension were prescribed an average of three antihypertensives. Combination of these drugs with the HAART regimen and opportunistic infection prophylactic drugs might result in non-adherence due to high pill burden and barrage of adverse effects (Haider *et al.*, 2009).

A thorough review of patients' medication profile showed that nevirapine could have interacted with fluconazole in 9.68% of the patients thereby resulting in an increase risk of hepatotoxicity. Interaction between stavudine and isoniazid can result in aggravation of peripheral neuropathy as this combination was seen in 13% of the patients, although 25mg daily dose of pyridoxine was prescribed to alleviate the condition. The interaction problem that could have resulted from combination of lamivudine and cotrimoxazole was mitigated with the adjustment of cotrimoxazole dose to 960 mg daily.

Drug adverse effects constitute major challenge to patient's adherence to medications and among the most common reasons for switching or discontinuation of therapy (O'Brein *et al.*, 2003). In this present study, three patients had regimen switched because of adverse effects while a female patient had her HAART regimen discontinued due to serious adverse effect (Stevens Johnson syndrome). Generally, patients were able to tolerate their medications due to transient nature of most of the adverse effects reported.

Concerning therapeutic response to HAART as measured by change in patients' CD4 count, 82.86% of patients recorded an increase of >50 cells/ μ L after 6-12 months period of therapy. An adequate CD4 response to HAART is defined as an increase in the range of 50-150 cells/ μ L for first year of therapy and increases that average 50-100 cells/ μ L for subsequent years until a steady state is reached (Kaufmann *et al.*, 2003). In the present study, it could be concluded that 82.86% therapeutic success was achieved 6-12 months after HAART.

In this study, there was a significant difference ($p < 0.01$) in the change in CD4 count among male and female patients as female patients recorded higher CD4 count changes (mean CD4 count increased from 108.5 ± 59.10 cells/ μ L to 303.5 ± 130.30 cells/ μ L) when compared to their male counterparts (mean CD4 count increased from 81.31 ± 77.80 cells/ μ L to 206.85 ± 142.42 cells/ μ L) 6-12 months after initiation of HAART. This finding was in line with the work of Thomas et al (2003) which reported greater CD4 cell count increases for women compared to men 6 months after HAART (Giordano *et al.*, 2003). Also in this study, there was no significant correlation between patient's age and change in CD4 count 6-12 months after initiation of therapy ($p > 0.05$). The present finding is contrary to the findings of Manfredi and Chiodo which reported significant correlation between patient's age and CD4 count after one year of HAART (Manfredi and Chiodo, 2000). However, there was a significant positive correlation ($p < 0.05$) between age and change in CD4 count within male patients but there was no significant correlation ($p > 0.05$) between age and change in CD4 count within female patients. As regards baseline CD4 count value, there was a significant positive correlation ($p < 0.05$) between baseline CD4 count value and change in patients CD4 count among patients and also within female patients but there was no significant correlation between baseline CD4 count value and change in CD4 count within male patients ($p > 0.05$). In conclusion, this study has showed that rational use of HAART in the management of HIV/AIDS can lead to significant improvement in most patients' immunological status and invariably quality of life. However, full benefits of HAART can only be realized, if patients report for treatment on time and adhere to prescribed drug therapy.

RECOMMENDATIONS

In order to curtail the spread of HIV/AIDS and to effectively manage those already infected, the following measures are suggested;

- There should be an intensification of public awareness campaign on HIV/AIDS;
- More voluntary counseling and testing (VCT), and treatment centre should be established, especially in the rural areas;
- There should be a legalization against discrimination of people living with HIV/AIDS;
- All aspects of HIV/AIDS management including laboratory services and drugs should be made free;
- All the three (3) classes of antiretroviral drugs including the protease inhibitors should be made available;
- Adherence counseling should be given to patients before initiation of therapy and at

every clinic visit;

- Patients evaluation tests such as CD4 count, liver function test (LFT), plasma HIV RNA, full blood count and basic chemical test should be performed at stated intervals;
- Efforts should be intensified to get a permanent cure for HIV/AIDS.

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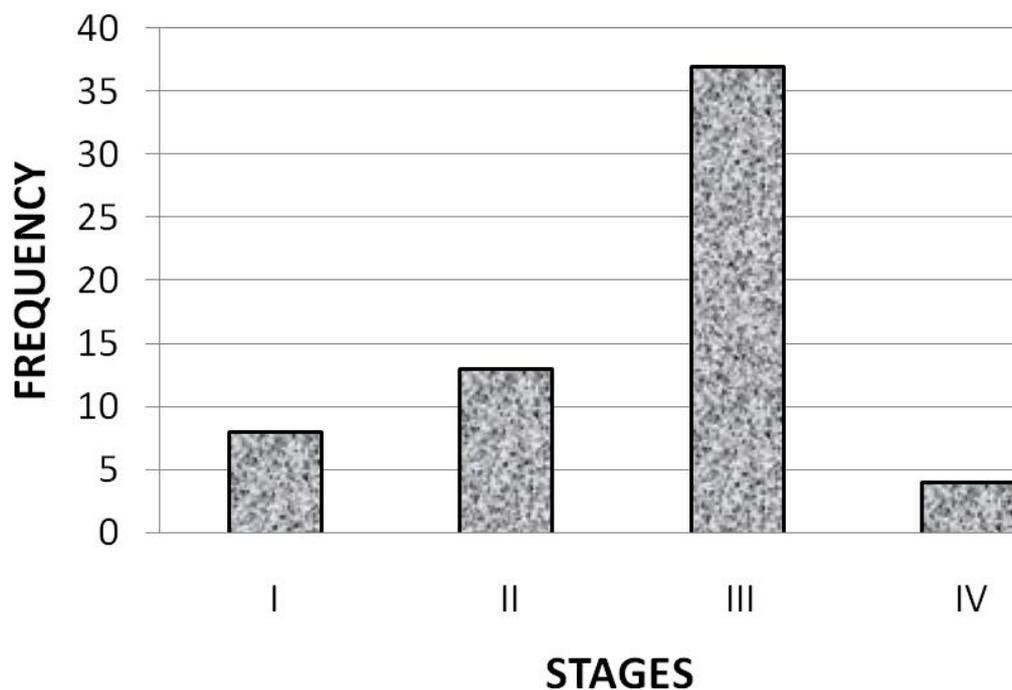


Figure1. Bar chart showing patients categorization based on clinical staging system.

Table 1. Analysis of patient CD4 count at Baseline.

CD4 count (cells/μL)	Frequency	Percent
1-50	20	35.71
51-100	10	17.86
101-150	17	30.35
151-200	7	12.50
201-250	1	1.79
251-300	1	1.79
Total	56	100.00

Data extracted from the patients' case notes obtained from the Medical Records department

Table 2. HAART Regimen used as first line

Regimen	Frequency	Percent
d4T/3TC/NEV	54	87.10
d4T/3TC/EFV	8	12.90
Total	62	100.00

Data extracted from the patients' case notes obtained from the Medical Records department

Table 3. Co-Infections and co-morbidities reviewed.

Disease	Frequency	Percent
Co-Infection		
Candidiasis	7	11.30
Malaria	22	35.48
Pulmonary tuberculosis	8	13.00
Upper respiratory tract infections	9	14.52
Others	9	14.52
Co-morbidity		
Hypertension	12	19.35

Data extracted from the patients' case notes obtained from the Medical Records department

TABLE 4. CONCOMITANT DRUGS PRESCRIBED

Class of Drug	Frequency of prescriptions
Antibacterials	111
Analgesics	22
Antimalarials	37
Antihistamines	23
Antihypertensives	45
Antimicrobials	12
Antifungals (oral)	6
Benzodiazepines	7
Multivitamins/ Minerals	78
Other drugs	41

Data extracted from the patients' case notes obtained from the Medical Records department

Table 5. Possible interactions between concurrent drugs and ARVs prescribed

Drug	ARV	Frequency	Percent
Fluconazole	Nevirapine	6	9.68
Isoniazid	Stavudine	8	13.00
Cotrimoxazole	Lamivudine	62	100.00
Rifampicin	Nevirapine	1	1.61

Data extracted from the patients' case notes obtained from the Medical Records department

Table 6. Documented Adverse Effects

Adverse Effect	Frequency	Percent
Pain	12	19.35
Diarrhoea	9	14.52
Weakness/Fatigue	3	4.84
Hallucinations	1	1.61
Headache	3	4.84
Insomnia	7	11.29
Itching	13	20.97
Paraesthesia	6	9.68
Peripheral neuropathy	2	3.23
Rash	10	16.13
Stevens Johnson Syndrome	1	1.61
Hearing loss	1	1.61
Vomiting	3	4.84

Data extracted from the patients' case notes obtained from the Medical Records department

Table 7. Change in patient CD4 count 6-12 months after initiation of HAART (n=35).

Patient No	Age (years)	Gender	CD4 count (cells/ μ L)		
			Baseline	6-12 months	Difference
1	30	F	160	499	339
2	52	M	4	119	115
3	39	F	94	133	39
4	28	M	15	18	3
5	40	M	124	269	145
6	32	F	126	424	298
7	36	F	114	139	25
8	52	F	146	334	188
9	31	F	33	119	86
10	30	F	30	269	239
11	32	M	147	182	35
12	33	F	189	510	321
13	42	M	278	482	204
14	39	M	14	206	192
15	40	M	143	267	124
16	45	F	50	145	95
17	41	M	17	264	247
18	37	M	75	41	-34
19	53	F	39	173	134
20	42	M	50	185	135
21	30	F	20	204	184
22	28	F	126	392	266
23	34	M	29	140	111
24	40	M	105	452	347
25	27	F	111	316	205
26	25	F	177	394	217
27	40	F	212	313	101
28	16	M	56	64	8

29	30	F	11	118	107
30	30	F	104	302	198
31	30	F	98	230	132
32	26	F	183	436	253
33	58	F	78	352	274
34	30	F	139	487	348
35	50	F	147	388	241

- Abbreviations, M-male, F-female
- Data extracted from the patients' case notes obtained from the Medical Records department