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ASSESSMENT OF HIGHLY ACTIVE ANTI-RETROVIRAL THERAPY OUTCOMES AMONG HIV INFECTED ADULT PATIENTS IN JIMMA UNIVERSITY SPECIALIZED HOSPITAL, JIMMA, SOUTH WEST ETHIOPIA

PROCENA ISHODA VISOKOAKTIVNE ANTI-RETROVIRUSNE TERAPIJE KOD ODRASLIH PACIJENATA ZARAŽENIH HIV VIRUSOM U JIMMA UNIVERZITATSKOJ SPECIJALIZOVANOJ BOLNICI, JIMMA, JUGOZAPADNA ETIOPIJA

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HIV/AIDS, ARV treatment outcome, CD4, HAART

Ključne reči
HIV/AIDS, ARV režim ishod, CD4, HAART

Abstract

Background: Development of highly active antiretroviral therapy (HAART) in the mid-1990s revolutionized in the care of HIV-infected patients leading into significant reductions in HIV-associated morbidity and mortality in many industrialized countries. **Objective:** The present study represents the assessment of antiretroviral therapy outcomes among adults on HAART in Jimma University Specialized Hospital. **Methods:** A Retrospective treatment outcomes of antiretroviral therapy among adult patients on HAART was conducted based on patient medical history records. **Results:** In the present study of 324 HIV infected patients 114 (35.2%) male and 210 (64.8%) female patients were included. About one third of them (34.6%) were in the age group between 31 and 40 years. From the total of 324 patient 265 of them were observed for their body mass index (BMI) at the base line of which 173 (65.3%) were underweight. The majority of patients, exactly 191 (58.95%), CD4 cell counts at the base line were in range ≤200. Most of the patients, 200 (61.7%), did not develop opportunistic infection after initiating HAART. The frequent initial antiretroviral (ARV) treatment applied to the patients was TDF-3TC-EFV, in 108 (33.3%). Of the total initial antiretroviral (ARV) treatment applied there were 103 changes reported within the first line. Additionally, from their initial antiretroviral (ARV) treatment applied there were 18 (5.56%) switching to second line. Concerning the adherence of patient to the HAART 299 (92.3%) were good. **Conclusion:** HAART is a key component of clinical care for HIV/AIDS patients. Additionally, routinely follow-up care after antiretroviral treatment (ART) initiation is necessary to maintain viral suppression, minimize side effects and delay disease progression. CD4 cell count, BMI, stage of the patient, initial ARV treatment, opportunistic infection and patient's adherence were the major parameters for the outcome of the treatment in this study. TDF-3TC-EFV were the most promising drug for initial ARV treatment.

INTRODUCTION

Development of highly active antiretroviral therapy (HAART) in the mid-1990s revolutionized the care of HIV-infected patients was leading into significant reductions in HIV-associated morbidity and mortality in many industrialized countries. According to estimation by the World Health Organization (WHO), about 6 650 000 patients were receiving antiretroviral therapy (ART) in low- and middle-income countries by the end of 2010. This is a huge improvement from the levels in 2003 [(1)]. The primary goals of antiretroviral therapy are preventing HIV-related morbidity and mor-

tality, and improving quality of life by restoring immunologic function through suppression of viral load [1]. Countries such as Ethiopia, Zambia, Namibia and Senegal are moving closer to the same target having covered 50-80% of patients in need of treatment [1, 2].

Cambodia is the country with one of the highest HIV prevalence in south-east Asia and access to ART is still limited. By the end of June 2006, almost 16,000 of the 30,000 patients supposed to be in immediate need of effectively received ART. Most were already at an advanced stage of HIV disease when entering the programme: 192 (46.0%) were at WHO stage III and 204 (48.9%) were at WHO stage IV. The body mass index (BMI) was below 18.0 kg/m^2 for 161 out of 387 patients (41.6%) and was below 15.0 kg/m^2 for 40 out of 387 patients (10.3%) [6].

In Brazil a public health programmed provides treatment to more than 130,000 Brazilians with HIV infection. The median baseline CD4+ was 211 cells/mL and the median baseline viral load (log10) was 4.9. The median duration of treatment was 16 months. Ninety-two patients (44%) have never had an opportunistic disease (OD), 95 patients (45%) experienced at least one OD before starting ART, 10 patients (5%) had an OD after starting ART, and 14 patients (7%) had an OD before and after starting ART [7].

Epidemiological surveillance of HIV/AIDS in Nigeria showed an increasing prevalence from 0.000001% in 1986 to 0.22% in 1987, 1.8% in 1991, 3% in 1992, 3.8% in 1993, 4.5% in 1996, 5.4% in 1999, and 5.8% in 2001 [8]. The epidemic in Nigeria can be described as heterogeneous, with various communities in different stages. Young people aged 15 to 24 years old comprise a large proportion of those infected. The Nigerian ART guideline for initiating therapy in adults and adolescents is dependent on WHO clinical staging and availability of CD4-cell count testing, and endorses largely the WHO guideline on ART initiation [8]. In Mozambique, where about 1.6 million people are HIV-infected and about 473,000 need ART, numbers of adult patients (≥15 years old) enrolled on ART have increased about 16-fold from less than 5,000 to 79,500 during 2004-2007 [9].

AIDS disease has been one of the most destructive epidemics to hit Ethiopia. There were 977,394 people living with the virus, and 258,264 of them require ART. Adults and adolescents account for 24% of antiretroviral (ARV) service coverage by December 2006[1]. A Federal Ministry of Health (FMOH) reports from 2007 and 2008 showed that 95,756 patients started ART treatment in Ethiopia, and that 71,773 (74.95%) of them were on ART [10,11]. In Ethiopia, there were more than 222,000 patients on antiretroviral treatment at the end of 2010. ART has improved survival and quality of life of patients with HIV/AIDS in the country. In Ethiopia, there are no studies reported the long term survival of patients on ART. Such studies could provide valuable information to evaluate the ART program in the country [5].

The ART program in Ethiopia has provided both survival and immunological benefits to many people living with HIV and AIDS (PLWHAs), and its outcomes are similar to those of ART programs in other countries. Retention of patients in care remains a major challenge, and it is highly variable among health facilities, with high, medium and low retention rates. Moreover, early initiation of patients on HAART should be considered seriously as many patients were started on HAART late in the course of their disease: 79% of patients on ART had baseline CD4-cell counts less than 200 cells per micro-liter. Finally, the shift to second-line ART require close monitoring to make sure that patients are not taking a failed treatment [12].

In Ethiopia, first-line ART treatment recommends that two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) and efavirenz (EFV) (a non-nucleoside reverse transcriptase inhibitor [NNRTI]) are combined in the first line ART treatment. There are several ways of combining the NRTI backbone [13]. However, from 5,642 patients with known baseline WHO stage classifications, 282 (5%) were in WHO stage I, 780 (13.8%) in stage II and 4,580 (81.5%) in stage III or IV [14].

This study was conducted to assess the treatment outcome of antiretroviral drugs on HIV patients and determine the major risk factor associated with the treatment response. There are no previous studies done about the treatment outcome of the ARV drug and associated major risk factor in Jimma University specialized hospital. Therefore, this study gives some clue about the change in treatment outcome of the ARV treatment on adult HIV patients and determine the major risk factor with the treatment response, which is important to give recommendation for concerned government and non government organization for future improvement of the ART drug outcome.

MATERIALS AND METHODS

Study area and period

The study was conducted in Jimma University Specialized Hospital in Jimma town, Ethiopia. Based on figures from the Central Statistical Agency, CSA in 2007 of Ethiopia; the total number of population in Jimma town is 120,600 [15]. Jimma University Specialized Hospital is one of the oldest public hospitals in the country. It was established in 1930 E.C. Currently it is the only teaching and referral hospital in the south western part of the country with capacity of 450 beds and a total of more than 1000 staffs of both supportive and professional which provide medical services like clinical services, laboratory and pathology, pharmacy services, radiology and other services. The study was conducted in ART clinic of the hospital from January 28 to February 8/ 2013.

Study design

A retrospective cross-sectional study was conducted using patient medical history records (individual patient cards). All important data were collected from the patient information cards using appropriate data collection format.

Source and Study Population

The source population was all cards of ART clinic patients at JUSH. The study population was HIV infected adults with age of ≥18 years and received care from ART clinic at JUSH, who had taken antiretroviral treatment at most for three years. Patients who had baseline clinical and immunological characteristics within three years after initiating their antiretroviral treatment were included in the study to compare their improvements; and patients who were on

ART for less than six months. Those patients with incomplete medical records, patients whose addresses were not known and who were not on treatment were excluded.

Sample size determination and sampling technique

The source of population was total number whoever enrolled in ART service i.e., 6651 (pre ART and ART) and those who were active during the study period is 2266 (all adults and pediatrics) of these 2099 were adults which are the study population. The sample size was estimated a single population proportion formula with finite population correction was used. The parameters like 50% prevalence, 95% confidence interval and 5% margin of error were considered for sample size determination [16]. The size of the study population obtained from the ART clinic was 2099. With the above assumptions, the adjusted sample size was 324. All cards of patients who fulfill the inclusion criteria was selected using systematic random sampling technique until the required sample obtained and the first card number selected by using lottery method from registered card list.

Data collection technique, processing and analysis

The data collection format was pretested before the actual data collection.The pre -test was made to evaluate the data collection format for its validity, reliability and consistency on 5% of the study population. Then the data were collected from individual cards of ART clinic patients who had taken antiretroviral treatment using data collection format. The data were collected, then cleared, coded, categorized and all data collected were analyzed using the Statistical Package for the Social Sciences (SPSS) version 19.0 software and interpreted. The results were compared with the set criteria and was presented in tables and figures. The data collection was closely supervised. Data clearing was done every day and formats with insufficient information were excluded from the study.

Ethical consideration

Formal letter was written from department of pharmacy to JUSH in order to get permission to conduct the study. The confidentiality of the patient records was maintained throughout the study period and names were not included in the abstracted data.

RESULTS

Data were collected from January 28 to February 8, 2013. During the study time 324 HIV care / ART follow-up form were included. 114 (35.2%) were male and 210 (64.8%) were female. From the study, 146 (46.0%) were married, 73 (22.5%) were divorced or separated, 60 (18.5%) were single and finally 42 (13%) were widowed. About one third of them were in the age group between 31 and 40 years (34.6%) followed by aged 21 to 30 years (28.3%). The educational status of most patients were primary education, 134 (41.4%), followed by secondary education 117 (36.1%). Over half of the patient 167 (51.5%) were orthodox in their religion. The occupational status of the majority of patients who use HAART (34.3%) was not employed (Table 1).

***Table 1**: Socio-demographic characteristics of patients using HAART in JUSH ART clinic*

Socio demographic characteristics	Records	
	Frequency	Percent (%)
Sex		
Male	114	35.2
Female	210	64.8
Total	324	100
Age group		
11-20	3	0.93
21-30	92	28.39
31-40	112	34.56
41-50	79	24.4
51-60	36	11.11
> 61	2	0.62
Educational status		
No education	45	13.9
Primary education	134	41.4
Secondary education	117	36.1
Tertiary education	28	8.6
Marital Status		
Single	60	18.5
Married	149	46.0
Widowed	42	13
Divorced/separated	73	22.5
Occupational status		
Employed full time	66	20.4
Not employed	111	34.3
Student	10	3.1
Self employed	94	29
Irregular employment	43	13.3
Religion		
Muslim	108	33.3
Orthodox	167	51.5
Protestant	34	10.5
Catholic	14	4.3
Other	1	0.3

From the total of 324 patients, for 265 was done their BMI at the base line. At that period 173 (65.3%) patients were underweight. But after 6 month of their treatment most patients were improved their BMI, and after 30 months on HAART, BMI of majority of patients was normal, from 18.5 to 24.9. However overweight and obese were not recorded as much (Table 2).

***Table 2**: Body mass index (BMI) of HIV patient on HAART from base line to 30 months in 6 months interval in JUSH ART* clinic

BMI	Base line		6 months		12 months		18 months		24 months		30 months	
	Fr	%	Fr	%	Fr	%	Fr	%	Fr	%	Fr	%
Under	173	65.3	138	52.08	132	54.55	106	49.3	86	50	54	41.86
Normal	89	33.58	124	46.79	103	42.56	102	47.44	83	48.26	73	56.59
Overweight	3	1.13	3	1.13	6	2.48	5	2.33	2	1.16	1	0.78
Obese	0	0	0	0	1	0.48	2	0.93	1	0.58	1	0.78
Total	265	100	265	100	242	100	215	100	172	100	129	100

Figure 1: *Change of mean BMI of patients during follow up period at JUSH ART clinic*

As shown in figure 1 the mean BMI at base line was 17.92 kg/m^2, after 6 months of their treatment patients were improved in their BMI by 0.64kg/m^2. The change in every interval was decreased from time to time but the change from 24 to 30 month was increased by 0.25kg/m^2.

Table 3: *CD4 cells count of HIV patients on HAART from base line to 30 months in 6 month interval at JUSH ART clinic*

CD4 cell count	Base line		6 months		12 months		18 months		24 months		30 months	
	Fr	%	Fr	%	Fr	%	Fr	%	Fr	%	Fr	%
≤200	191	58.95	83	31.2	39	19.9	21	11.67	14	11.11	4	4.76
200-350	105	32.41	139	52.26	84	42.86	55	30.56	38	30.16	22	26.19
≥350	28	8.64	44	16.54	73	37.25	104	57.8	74	58.73	58	69.05
Total	324	100	266	100	196	100	180	100	126	100	84	100

For majority of patients CD4 cell counts at the base line were in range ≤200, 191 (58.95%) (Table 3). But after 6 month and during the same interval up to 30 months, CD4 cell count for most patients increased from time to time. Especially those taking the drug for 30 months and their CD4 cell count were above ≥350 in more than 65% of patients.

Figure 2: *Change of mean CD4 cells count of patients during follow up period at JUSH ART clinic*

As depicted in figure 2 the mean CD4 cell count at base line was 189.15 cells/mm^3, after 6 month of their treatment patients were improved their mean CD4 cell count by 73.56 cells/mm^3. The change in every 6 months interval was 73.56 cell/mm^3, 56.26 cell/mm3, 59.55 cell/mm^3, 14.94 cell/mm^3 and 53.93 cell/mm^3 respectively.

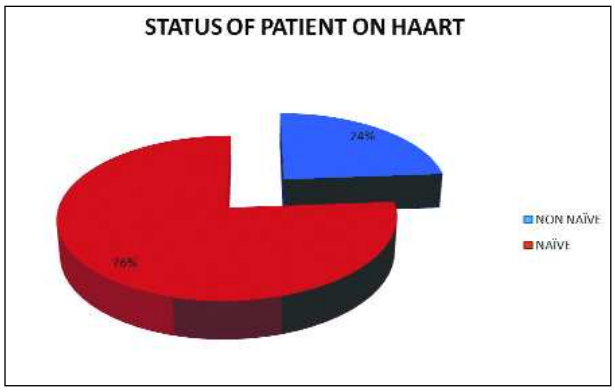

Figure 3: *Status of patients on HAART at JUSH ART clinic*

About 247 (76%) of the patients had naive for antiretroviral treatment and the rest 77 (24%) were non naive for the treatment (Figure 3).

Table 4: *Opportunistic Infections (OI) developed after initiating HAART at JUSH* ART clinic

Opportunistic infection (OI)	Frequency	Percent (%)
None	200	61.7
Chronic diarrhea	8	2.5
Chronic diarrhea, TB-IRIS	1	0.3
CNS toxoplasmosis	1	0.3
Extra pulmonary TB	22	6.8
Fever >1month	2	0.6
Oropharyngeal candidiasis	1	0.3
PCP (Pneumocystis carini) pneumonia pneumonia)	2	0.6
PCP, herpes zoster	1	0.3
Pulmonary TB	79	24.4
TB-IRIS	6	1.9
Vulvo vaginal candidiasis	1	0.3
Total	324	100.0

The majority of patients did not develop opportunistic infection after initiating HAART 200 (61.7%) (Table 4). However, from the remaining 124, pulmonary tuberculosis (TB) covers high percent 79 (24.4%) followed by extra pulmonary TB 22 (6.8%).Opportunistic infection like chronic diarrhea, TB-IRIS (Immune Reconstitution Inflammatory Syndrome) and Pneumocystis carinii pneumonia (PCP) developed in 8 (2.5%), 6 (1.9%) and 2 (0.6%) respectively. The others, like chronic diarrhea + TB-IRIS, CNS toxoplasmosis, oropharyngeal candidiasis, PCP + herpes zooster, and vulvo vaginal candidiasis each of them covers 1 (0.3%).

Regarding the WHO clinical stage of the patients, 138 (42.6%) were stage III followed by 90 (27.8%) stage II

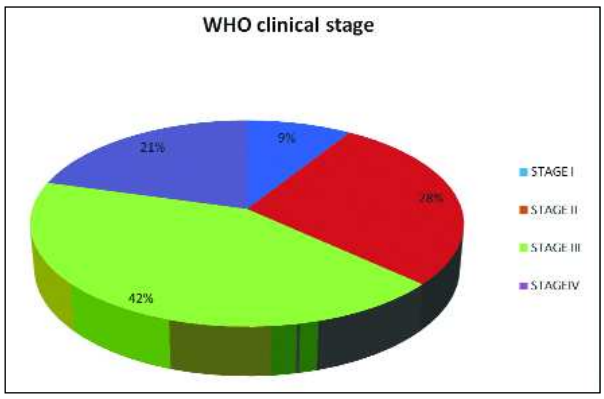

Figure 4: *WHO clinical stage of patients on HAART at JUSH ART clinic*

(Figure 4). Stage I and Stage IV account 29 (9.0%) and 67 (20.7%) respectively. Most patients were in stage III during the initiation of the treatment.

Table 5*: Initial ARV regimen for adult HIV infected patients at JUSH ART clinic*

Initial ARV regimen	Frequency	Percent (%)
ABC-3TC-EFV	1	0.3
ABC-3TC-NVP	1	0.3
D4T-3TC-EFV	12	3.7
D4T-3TC-NVP	94	29
ZDV-3TC-EFV	21	6.5
ZDV-3TC-NVP	65	20.1
TDF-3TC-NVP	22	6.8
TDF-3TC-EFV	108	33.3
Total	324	100.0

The most frequent initial ARV regimen given for the patient was TDF-3TC-EFV 108 (33.3%) following with D4T-3TC-NVP 94 (29.0%) (Table 5). The others where ABC-3TC-EFV 1 (0.3%), ABC-3TC-NVP 1 (0.3%), D4T-3TC-EFV (3.7%), ZDV-3TC-EFV 21 (6.5%), ZDV-3TC-NVP 65 (20.1%), TDF-3TC-NVP 22 (6.8%).

Table 6: *Changes within the first line ARV regimen for adult HIV infected patients at JUSH ART clinic*

ARV regimen	Frequency	Percent (%)
ZDV-3TC-NVP	51	49.5
TDF-3TC-NVP	24	23.3
TDF-3TC-EFV	18	17.5
ZDV-3TC-EFV	8	7.8
D4T-3TC-NVP	1	0.97
ABC-3TC-NVP	1	0.97
Total	103	100.0

Of the total initial ARV treatment applied, there were 103 changes within first line documented (Table 6). The major causes of changes were toxicity/side effect 83 (80.58%), virologic failure 10 (9.71%) and pregnancy 7 (6.8%). The other percentage are due to new TB 3 (2.91%). ZDV-3TC-NVP 51 (49.5%) and TDF-3TC-NVP 24 (23.3%) mostly prescribed drug for patient during regimen changed. ARV regimen TDF-3TC-EFV, ZDV-3TC-EFV, D4T-3TC-NVP and ABC-3TC-NVP comprises 18 (17.5%), 8 (7.8%), 1 (0.97%) and 1 (0.97%) respectively.

Table 7: *Switching from first line ARV regimen to second line and the applied drug for adult HIV infected patients at JUSH ART clinic*

ARV regimen	Frequency	Percent (%)
ABC-3TC-LPV/r	2	11.11
ABC-DDI-LPV/r	11	61.11
ABC-TDF-LPV/r	1	5.56
ZDV-3TC-LPV/r	4	22.22
Total	18	100.0

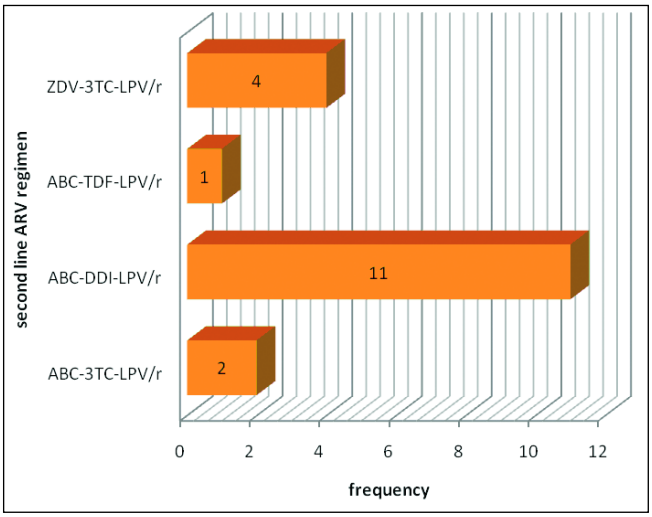

Figure 5: *Second line ARV regimen applied for the patients at JUSH ART clinic*

Of the total 324 patients in 18 (5.56%) their initial ARV regimen was switched to the second line (Table 7, Figure 5).

Table 8: *Reason for switching ARV regimen at JUSH ART clinic*

Reason for switching	Frequency	Percent (%)
Toxicity /side effect	3	16.67
Treatment failure	13	72.22
Virologic failure	2	11.11
Total	18	100.00

The major causes of switching initial ARV regimen were treatment failure, in 13 (72.22%) followed by toxicity/side effect in 3 (16.67%) and finally virologic failure in 2 (11.11%) patients (Table 8). ABC-DDI-LPV/r was more frequent prescribed drug, in 11 (61.11%) patients, followed by ZDV-3TC-LPV/r (22.22%), ABC-3TC-LPV/r 2 (11.11%) and ABC-TDF-LPV/r 1 (5.56%).

Table 9: *Side effect seen on the patients after taking HAART at JUSH ART clinic*

Side effect and adverse effect	Frequency	Percent (%)
Abdominal pain	3	5.17
Diarrhea	1	1.72
Fat change	7	12.1
Fatigue	25	43.1
Fatigue , Headache	2	3.45
Headache	11	18.96
Nausea	5	8.62
Nausea, Fatigue	1	1.72
Peripheral neuropathy	2	3.45
Rash	1	1.72
Total	58	100.0

From the total of 324 patient who were receiving treatment, there were only 58 (17.9%) patients with side effects (Table 9). The major side effects seen were fatigue 25 (43.1%), and headache 11 (18.96%), and the least side effects seen were diarrhea, rash and nausea + fatigue each accounts 1 (1.72%).

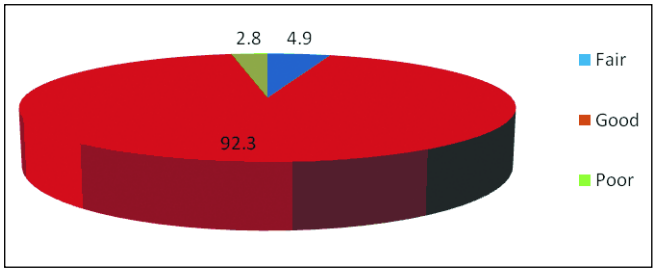

Figure 6: *Adherence of patients to the HAART at JUSH ART clinic*

Concerning adherence of patient to the HAART, 299 (92.3%) were good followed by fair 16 (4.9%) and finally poor accounts 9 (2.8%).

DISCUSSION

In 2010, WHO issued revised treatment guidelines recommending all adolescents and adults including pregnant women with HIV infection and CD4 counts of ≤350 cells/mm3, should start ART, regardless of the presence or absence of clinical symptoms [1]. Those with severe or advanced clinical disease (WHO clinical stage 3 or 4) should start ART irrespective of their CD4 cell count. These new criteria increased the total number of people medically eligible for antiretroviral therapy by roughly 50%-from 10 million to 15 million in 2009 [3]. But in this study, 138 (42.6%) patients that started HAART were in WHO clinical stage 3, and 67 (20.7%) were in stage 4, irrespective of their CD4 cell count or in stage 1, 29 (9%) and stage 2, 90 (27.8%) with CD4 count ≤ 200 regardless of the presence or absence of clinical symptoms. This was done according to 2006 ART guideline but the strategy was changed in this year according to 2010 ART guideline.

Slightly more than half of all people living with HIV are women and girls [1]. In sub-Saharan Africa, more women than men are living with HIV, and young women aged 15-24 years are as much as eight times more likely than men to be HIV positive. Protecting women and girls from HIV means protecting against gender based violence and promoting economic independence from older men [3]. In present study the percentage of men living with HIV were slightly more than half of women. HIV prevalence among women aged 21 to 30 years was 74 (22.84%), what was four times more than that of the prevalence among young men 18 (5.56%) in the same age group.

In Brazil the median baseline CD4+ was 211 cells/mL and the median baseline viral load (log10) was 4.9. The median time on treatment was 16 months. Ninety-two patients (44%) never had an opportunistic disease (OD), 95 patients (45%) experienced at least one OD before starting ART, 10 patients (5%) had an OD after starting ART, and 14 patients (7%) had an OD before and after starting ART [7]. In present study the median base line CD4+ was 175.5 cells/mL but after that in every 6 month interval for consecutive 30 months the median CD4 cell count was increased from time to time. At month 6, 12, 18, 24 and 30 median CD4 cell count 257 cells/mL, 305 cells/mL, 365 cells/mL, 394 cells/mL and 458.5 cells/mL respectively. The majority of patients CD4 cell count at the base line were range ≤200, 191 (58.95%) and after 30 month out of 84 patients 58 (69.05%) were CD4 cell count ≤350. The median time on treatment was 18 months. Out of 324, 124 patients experienced opportunistic infection after starting HAART. Of these 85 (26.23%) were female and 39 (12.04%) were male and also most of them are WHO clinical stage 2.

Cambodia presents one of the highest HIV prevalence's in south-east Asia. However, access to ART is still limited, and up to end of June 2006, almost 16 000 of the 30 000 patients supposed to be in immediate need of effectively received ART. Among the 2048 HIV-infected patients who were on HAART up to 31 March 2005 in the programme, 416 adults had started 24 months earlier and were included in the analysis. A total of 247 (59.2%) were men and the median age was 33.6 years [interquartile range (IQR) 30.1-38.2.] Almost all (396/416, 95.2%) were ART naive. Most were already at an advanced stage of HIV disease when entering the programmed: 192 (46.0%) were at WHO stage III and 204 (48.9%) were at WHO stage IV. The BMI was below 18.0 kg/m^2 for 161 (41.6%) out of 387 and was below 15.0 kg/m2 for 40 (10.3%) out of 387 patients [6]. In the present study 114 (35.2%) men and 210 (64.8%) female were involved and the median age was 36.5 years. Almost all (247/324, 76.2%) were ART naive. Most patients were in stage III 138 (42.6%) and followed by stage II 90 (27.8%). The body BMI was below 18.5 kg/m^2 for 173 (65.3%) out of 265 patients at the base line that means they are underweight. But after that in every 6 month interval for consecutive 30 months the BMI was increased from time to time. The median BMI from base line to 30 month at 0, 6, 12, 18, 24 and 30 month median BMI were 17.65 kg/m^2, 18.29 kg/m^2, 18.3 kg/m^2, 18.5 kg/m^2, 18.51 kg/m^2 and 18.8 kg/m^2 respectively.

In 2010, WHO issued revised treatment guidelines. There is a clear demand both from people living with HIV (PLHIV) and health-care providers to phase in less toxic ARVs while maintaining simplified fixed-dose combinations. The available evidence indicates that initial ART should contain an NNRTI (either NVP or EFV) plus two NRTIs, one of which should be 3TC or FTC and the other AZT or TDF. The toxicity of d4T is of concern to the majority of PLHIV and its continuing use may undermine confidence in ART. If d4T has to be included in ongoing regimens, strategies should be devised to allow for substituting an alternative drug in cases of toxicity. There should be a plan to eventually avoid the routine use of this drug [1]. In Ethiopia, first-line ART regimen is recommended that two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs) and efavirenz (EFV) (a non-nucleoside reverse transcriptase inhibitor [NNRTI]) be combined in the first line ART regimen. If EFV cannot be used, a ritonavir-boosted protease inhibitor (PI/r) or nevirapine (NVP) are alternatives, and use of a third nucleoside or raltegravir (RAL) is

acceptable. There are several ways of combining the NRTI backbone [13]. However, from 5,642 known baseline WHO stage classifications, 282 (5%) were in WHO stage I, 780 (13.8%) in stage II and 4,580 (81.5%) in stage III or IV. Of the 5,181 available CD4 cell counts measured at and three months before HAART initiation, 755 (14.6%) had CD4 cell count of less than 50/ml, 2,910 (56.2%) had between 50 and 200 per ml and 1,516 (29.2%) had above 199 cells per /ml. The median CD4 cell count was 140 cells per/ml. The mean (SD) baseline weight for 2,114 male and 3,092 female participants measured were 54 (8.4) and 47.7 (8.7), respectively. Functional status at start of ART initiation was 562 (10.4%), ambulatory 2,105 (39.0%) and working 2,725 (50.5%) [14]. In present study the available initial ARV drug contain one NNRTI (either NVP or EFV) plus two NRTIs, one of which should be 3TC and the other AZT, TDF or D4T. For those their regimen was D4T based, the toxicity of D4T is highly experienced. Because of this the preferred regimen was TDF and ZDV based. Therefore due to the reason of toxicity, in majority of patient whose initial ARV regimen was D4T based, it was changed within first line of ARV regimen. From the total of 324 patients 106 (32.72%) were D4T based. Initial ARV regimen was changed in 103 (31.8%) patients within first line. Out of 106 D4T based regimen 71 (21.91%) were changed within first line regimen. Drugs given to the patients during regimen change were ZDV-3TC-NVP 51 (49.5%). Additionally, there were also switching from first line to second line ARV regimen. These occurred in 18 (5.6%) patients. The main reason for switching ARV regimen was treatment failure, in 13 (72.22%). From second line ARV regimen, ABC-DDI-LPV/r 11 (61.11%) was mostly prescribed drug for the patient followed by ZDV-3TC-LPV/r 4 (22.22%). Adherence of patient to the HAART was good, around 92.3%.

CONCLUSION

This study displayed that HAART is a key component of clinical care for HIV/AIDS patients. Additionally, routinely follow-up care after ART initiation is necessary to maintain viral suppression, minimize side effects and delay disease progression. CD4 cell count, BMI, stage of the patient, initial ARV regimen, opportunistic infection, and adherence of the patient were the major parameter for the outcome of the treatment in this study. TDF-3TC-EFV was the most promising drug for initial ARV regimen. The majority of patients did not develop opportunistic infection after initiating HAART. The most common opportunistic infection during this period was pulmonary TB. In most patients the side effect seen was fatigue. Generally adherences of the patient to the treatment used were good.

It is better for the laboratory technicians to make the CD4 cell count machine functional all the time in order to control or decrease the gap. The physician, the nurse, and the pharmacist should cooperate in order to decrease the failure to document all the patients' information in their follow up card. It is good for pharmacist to follow the patient closely to monitor the drugs effect and also to decrease the toxicity/side effect of the drug. It is preferable to teach the patient about the use of HAART to increase adherence of the patient to the treatment.

Sažetak

Podaci: Razvoj visokoaktivnog antiretrovirusnog tretmana (HAART) sredinom devedesetih godina predstavlja revoluciju u nezi HIV-om zaraženih pacijenata, što je dovelo do smanjenja morbiditeta i mortaliteta povezanih sa HIV-om u industrijalizovanim zemljama. Cilj: Cilj studije je bio da se proceni ishod antiretrovirusne terapije medju odraslim pacijentima u specijalizovanoj bolnici na Jima Univerzitetu. Metoda: Retrospektiva HAART tretmana kod odraslih pacijenata je uradjena na osnovu medicinskih istorija. Rezultati: U studiju je bilo uključeno ukupno 324 pacijenta od kojih su 114 (35,2%) bili muškarci, a 210 (64,8%) žene. Jednu trećinu ispitanika (34,6%) su činili pripadnici starosne grupe od 31 - 40 godina. Od 265 pacijenata kod kojih je BMI kontrolisan na početku terapije, kod 173 (65,3%) je bio ispod normalnog. Kod više od polovine pacijenata, tačnije 191 (58,95%), broj CD4 ćelija na početku terapije bio je u opsegu ? 200. Većina pacijenata, njih 200 (61,7%), nije razvila oportunističke infekcije nakon početka HAART. Najčešći početni ARV režim lečenja bio je TDF-3TK-EFV, kod 108 (33,3%) pacijenata. U odnosu na sve početne ARV režime lečenja, 103 promene su napravljene kod lekova prve linije. Pored toga, 18 (5,56%) promena početnog ARV režima lečenja je bilo prema lekovima druge linije. Kada se analizira odgovor pacijenata na HAART, kod njih 299 (92,3%) je bio dobar. Zaključak: HAART je ključna komponenta kliničke brige za HIV/AIDS pacijente. Dodatno, rutinsko praćenje i briga nakon otpočinjanja ART je neophodno da bi se virus držao pod supresijom, umanjili neželjeni efekti i odložilo napredovanje bolesti. Broj CD4 ćelija, BMI, faza pacijenta, početni ARV režim lečenja, oportunističke infekcije i odgovor pacijenata na terapiju, bili su glavni parametri za praćenje tretmana u izradi studije. TDF-3TK-EFV kombinacija je bila glavni kandidat za početni ARV režim lečenja.

REFERENCES

1. WHO, antiretroviral therapy for HIV infection in adults and adolescents Recommendations for a public health approach 2010 revision.

2. Lawn SD, Harries AD, Anglaret X, Myer L, Wood R. Early mortality among adults accessing antiretroviral treatment programmes in sub-saharan Africa. AIDS 2008; 22(15):1897-908.

3. Global report, UNAIDS report on the global aid epidemics, 2010.

4. Michael HC, Alison LD, Barbra AR, Ashok Reddy, Joan Thiga, Samah R S, et al. Impact of Prior HAART Use on Clinical Outcomes in a Large Kenyan HIV Treatment Program. Curr HIV Res. 2009; 7(4): 441-6.

5. Biadgilign S, Ayalu AR, Tesfaye D. Predictors of mortality among HIV infected patients taking antiretroviral treatment in Ethiopia: a retrospective cohort study. AIDS Research and Therapy 2012; 9(15), doi:10.1186/1742-6405-9-15

6. Laurent F, Didier L, Narom P, Chanchhaya N, Marcelo F, Loretxu P, et al. Positive outcomes of HAART at 24 months in HIV-infected patients in Cambodia. AIDS 2007; 21:2293-301.

7. Cristina B, Hofer, Mauro S, Lee HH. Effectiveness of Antiretroviral Therapy among Patients who Attend Public HIV Clinics in Rio de Janeiro, Brazil. J Acquir Immune Defic Syndr 2004; 36(4):967-71.

8. Kenneth AA, Uche MO, Azuka O, Obialunamma UO. Treatment Outcomes in Patients Receiving Combination Antiretroviral Therapy in Central Hospital, Benin City, Nigeria. Trop J Pharm Res. 2010; 9(1):1-10.

9. Andrew FA, Francisco M, Ray WS, Mauro S, Charity A, Lisa JN, et al. Four-Year Treatment Outcomes of Adult Patients Enrolled in Mozambique's Rapidly Expanding Antiretroviral Therapy Program. 2011;6(4) e18453; DOI: 10.1371/journal.pone.0018453.

10. FMOH. Aids in Ethiopia: Sixth Report, NationalHIV/AIDS Prevention and Control Program in Ethiopia. Addis Ababa, 2007.

11. FMOH. Health and health related indicators of 1999 E.C/2008, FMOH. Addis Ababa, 2008.

12. Yibeltal A, Abiyou K, Dessalegn T, Damen HM, Helmut K, Wouters E et al. Outcomes of antiretroviral treatment program in Ethiopia: Retention of patients in care is a major challenge and varies across health facilities. BMC Health Services Research. 2011;11:81.

13. Patient evaluation and antiretroviral treatment for adults and adolescents. Clinical Protocol for the WHO European Region (2012 revision).

14. Eyuel T, Alemayehu W. Assessment of antiretroviral treatment outcome in public hospitals, South Nations Nationalities and Peoples Region, Ethiopia. Ethiop. J. Health Dev. 2011; 25(2):102-9.

15. Federal democratic republic of Ethiopia population census commission, Summary and statistical report of the 2007 population and housing census, population size by age and sex, 2008 Addis Ababa.

16. Israel GD. Determining sample size. PEOD6, 1992. Revised 2009; Reviewed 2012. University of Florida IFAS extension. Available at: http://edis.ifas.ufl.edu/pd006.

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