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Prevalence of Diabetes Mellitus, Hypertension and Lipodystrophy in HAART Receiving HIV Patients in Southern Ethiopia

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Authors' contributions

This work was carried out in collaboration between all authors. Author VS gave suggestions for design of the study and critically reviewed the initial and final drafts of the manuscript. Author EL gave suggestions for design of the study and managed the statistical analyses of the study. Author MG gave suggestions for design of the study, managed the literature searches and wrote the first draft and incorporated suggestions in the final draft of the study. All authors read and approved the final manuscript.

Research Article

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ABSTRACT

Aims: In Ethiopia, AIDS has become the leading cause of mortality in the 15-49 years age group, accounting for an estimated 43% of all young adult deaths. Though the introduction of highly active antiretroviral therapy (HAART), improved survival and quality of life, early data from those treated, raised concerns about a possible increase in both peripheral and coronary arterial disease through lipodystrophy, diabetes mellitus and dyslipidemia. Hence an attempt was made in this study to understand risk factors of HIV positive subjects and prevalence of lipodystrophy, type II diabetes mellitus and hypertension in subjects receiving HAART.
Study Design: Institution based cross sectional and retrospective study was conducted.
Place and Duration of Study and Sample: Study participants were men and women who were HIV/AIDS patients receiving HAART from Sodo government hospital, Southern Ethiopia from December 1st, 2009 - January 30th, 2010.
Methodology: By using the subjects' electronic database as sampling frame, a total of 176 subjects were recruited for the study using simple random sampling method. Data was collected on socio demographic characteristics, HAART use, CD4 count, subjects' status at the start of treatment, measure of body fat distribution, physical activity, blood

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pressure and blood glucose.
Results: Prevalence of Diabetes mellitus was seen in 8% of the subjects. Hypertension was seen in 15.9% of the subjects. In multivariate analysis adjusted for age and duration of HAART both lipoatrophy and lipohypertrophy were significantly associated with diabetes mellitus while only lipohypertrophy (adjusted for age) remained to be significantly associated with hypertension.
Conclusion: Since lipoatrophy (adjusted for age and duration of HAART) was significantly associated with diabetes mellitus and lipohypertrophy (adjusted for age and duration of HAART) was associated with diabetes mellitus and (adjusted for age) was associated with hypertension, there is a need to investigate types of HAART regimens which do not lead to lipodystrophy and associated diabetes mellitus or hypertension in AIDS/HIV subjects.

Keywords: AIDS/HIV; HAART; risk factors; lipodystrophy; diabetes mellitus; hypertension.

1. INTRODUCTION

Ethiopia is one of the countries in Africa with a high prevalence rate of HIV/AIDS. At the end of 2005 a total of 1.3 million adults and children were living with HIV/AIDS. In the same year alone there were an estimated 128,900 new HIV infections and 134,500 AIDS deaths. Life expectancy is decreasing as a result of the epidemic and is expected to drop to 50 years by 2010. AIDS has become the leading cause of mortality in the 15-49 years age group, accounting for an estimated 43% of all young adult deaths. In the urban areas, nearly 66% of young adult deaths are estimated to be attributed to AIDS [1].

The introduction of highly active antiretroviral therapy (HAART) revolutionized the prognosis of HIV/AIDS. However, the use of such treatment regimen has coincided with the emergency of body fat distribution modification (lipodystrophy) and alteration in lipid and glucose metabolism, a condition known as lipodystrophic syndrome (LS) [2]. Though the introduction of HAART improved survival and quality of life, early data from those treated, raised concerns about a possible increase in both peripheral and coronary arterial disease through lipodystrophy, diabetes mellitus and dyslipidemia [3].

However, most patients continue to receive combination antiretroviral therapy, despite the associated abnormalities, because these medications provide them the best available therapy to control HIV viral replications and to maintain immunocompetence. Detection and management of this disorder helps to prevent further complications. Therefore research has been undertaken to find possible modifiable factors that can reduce the magnitude of the lipodystrophy syndrome in HAART receiving individuals. So far, studies have reported different risk factors associated with this abnormality [4], such as the toxic effect of the drug, life style (physical activity, smoking, and alcohol use), diet, age and ethnicity. Some other factors reported are, sex, CD4 count and duration and type of HAART [5].

Therefore, this study aims to determine the prevalence of lipodystrophy, type II diabetes mellitus and hypertension and the risk factors associated with these problems among HIV positive subjects receiving HAART at Sodo hospital. Identifying these factors will help to outline those which are modifiable and thus help to reduce the magnitude of lipodystrophy syndrome in HAART receiving individuals.

2. MATERIALS AND METHODS

Welayita Sodo is the zonal town of Welayita ethnic group found in Southern Nations and Nationalities Peoples Region (SNNPR), South of Ethiopia, 64 350 km away from the capital, Addis Ababa. It has a total of 75,000 residents mostly of Welayita ethnic group. The town has one government, two non government hospitals and one health center. Government supported free HIV/AIDS care including HAART was delivered in all of these institutions. Institution based cross sectional and retrospective study was conducted from December 1st, 2009-January 30th, 2010.

Study participants were men and women who were HIV/AIDS patients receiving HAART from Sodo government hospital, Southern Ethiopia. Only one hospital was chosen because the study was a short duration study and a majority of the patients visited this hospital. Patients were excluded if they had any active opportunistic infections in the past 3 months, were on anabolic or corticosteroid agents, if pregnant or using hormonal contraceptives, if critically ill and unable to undergo the assessment and had a family history of hypertension and or diabetes mellitus.

Subjects were included in the study if they were between the ages of 18 and 50 years, had documented HIV infection and were on HAART for > 6 months. Study subjects were screened by reviewing the subjects' health record and by interview using structured screening questions. By using the subjects' electronic database as sampling frame, a total of 176 subjects were recruited for the study using simple random sampling method. For estimation of the number of subjects to be selected for this study, data from a Rwandan study done by Mutimura and his colleagues [6] was utilized which reported lipodystrophy prevalence to be 34%.

Data were collected by interview on socio demographic characteristics such as age, sex, ethnicity, religion, educational status, income and functional status at the start of treatment. From the patient's health record, data on CD4 count at the start of treatment and during the last 6 months, stage of disease at the start of treatment, type and duration of HAART used in the last 3 months before the study period and weight at start of treatment were collected. Body fat distribution was assessed by patient's self report and physical examination done by a physician. Using a lipodystrophy specific standardized questionnaire, trained physicians working in the clinic determined whether the participants had more or less fat than healthy people in each of the same body areas as questioned during the interview using validated skin calipers. These data were used to assess the agreement between both lipodystrophy assessment methods.

The primary outcome was physician reported lipodystrophy at the time of examination. It was defined as a finding of moderate or severe change in any of the following parameters: fat loss in the face or arms; fat gain in the back or base of the neck; increase in breast size; decrease in fat on buttocks or legs; or lipomatosis. The presence of lipodystrophy was based on a subjective case definition previously developed and validated by Carr and his colleagues [7] but excluded clinical characteristics not generally recognized as manifestations of HIV associated lipodystrophy (i.e., fat gain in face, fat loss/gain in the front or sides of neck, fat gain in arms, decrease in breast size, increase in fat on buttocks or legs, and decrease in waist size). Consistent with the definition by Carr and his colleagues [7], patients reporting "moderate or severe isolated abdominal obesity" were excluded from analysis in order to avoid confounding by age-related central adiposity. The phenotypes of lipodystrophy were also examined: lipohypertrophy (defined as moderate or severe fat gain

in the back or base of the neck or increase in size of breast); lipoatrophy (defined as a moderate or severe fat loss in the face or arms, or decrease in fat on buttocks or legs); and reporting both fat gain (i.e. lipohypertrophy or lipomatosis) and fat loss (i.e. lipoatrophy) after the diagnosis of HIV infection [7].

The height and body weight were measured to a precision of 0.1 cm and 0.1 kg, respectively, utilizing a digital balance with height measurement attached to the digital balance. Body mass index (BMI) was calculated as a ratio between the weight in kilograms and the square of the height in meters [8].

Health workers from the hospital measured resting blood pressure using an automated sphygmomanometer according to a standardized protocol [9]. Values of blood pressure greater than 140/90mmHg were considered to be hypertensive [10].

Diagnosis of diabetes mellitus was made based on a single fasting blood glucose test using finger prick by enzymatic method [11]. Blood levels greater than or equal to 126g/dl were considered to be diabetic. Using a single fasting blood glucose measurement to assess the incidence of diabetes mellitus might have lead to an overestimation of its incidence and this is one of the limitations of the present study.

To evaluate the habitual physical activity, data on physical activity was collected using the questionnaire devised by Baecke and coworkers [12]. Since only a few subjects had the habit of leisure time physical exercise and regular physical exercise, level of physical activity was determined based on the subjects' self labeling of their work intensity according to their age. Thus, subjects rated their work intensity as 'much heavier', 'equally heavier' and 'much lighter'. This is a limitation of the present study since the subjects could have misjudged categorization of their activities. The goodness of fit to normal distribution was evaluated using the Kolmogorov-Smirnov test. The distribution of anthropometric measurements was compared for different patterns of fat redistribution and gender by Mann-Whitney and Kruskal-Wallis H test, and percentage difference by Chi-square test between categorical variables and or with 95% confidence interval.

Bivariate analysis was used to identify significant predictors of lipodystrophy, diabetes mellitus and hypertension. Independent variables showing significant association (p=0.05) during bivariate analysis were fed into multivariate models to control for confounding variables and analyzed using multivariate logistic regression.

Because only a few subjects had the habit of alcohol use, smoking and physical exercise, these factors were not tested for association with dependent variables. All significant test values were two sided and significant values considered at p = 0.05. Analysis was performed using SPSS version 12.

3. RESULTS

Overall prevalence of Diabetes mellitus was seen in 8% (95% CI: 4.1-11.9) of the subjects and hypertension was seen in 15.9% (95% CI: 10.5-21.3) of the subjects. Lipohypertrophic subjects had significantly higher prevalence of hypertension (p = 0.007, COR: 5.73, 95% CI: 1.46-22.58) and diabetes mellitus (p < 0.001, COR: 23.7, 95% CI: 4.88-122.5) than normal subjects. Lipoatrophy had no significant association with either diabetes mellitus or hypertension (p =0.71, COR: 3.38, 95% CI: 0.3-21.16 for diabetes mellitus). None of the

lipoatrophic subjects developed hypertension and no significant association was observed (Prevalence 0.0%, COR: 0.0, 95% CI: 0.0-1.6) (Tables 1 and 2).

Table 1. Prevalence of diabetes mellitus and different forms of lipodystrophy in HAART receiving HIV patients, Sodo town, Southern Ethiopia, 2010

Pattern of fat change	Prevalence of diabetes mellitus n (%)	COR(95% CI)	AOR(95%CI)
No lipodystrophy	6(3.4)	1	
Isolated peripheral lipoatrophy	2(1.1)	3.38(0.3-21.16)	10.1(1.2-86.3)*
Isolated lipohypertrophy	6(3.4)	23.7(4.9-122.5)*	29.6(2.7-328.2)*

**p = 0.05; adjusted for age and duration of HAART COR- crude odds ratio; AOR- adjusted odds ratio.*

Table 2. Association of hypertension with different forms of lipodystrophy in HAART receiving HIV patients, Sodo town, Southern Ethiopia, 2010

Pattern of fat change	Prevalence of hypertension n (%)	COR(CI)	AOR(95%CI)
No lipodystrophy	22(12.5)	1	1
Isolated peripheral lipoatrophy	0(0.0)	0.0(0.0-1.6)	-
Isolated lipohypertrophy	6(3.4)	5.73(1.46-22.6)*	5.8(1.7-20.6)*

**p = 0.05 adjusted for age; COR – crude odds ratio; AOR – adjusted odds ratio.*

In bivariate analysis, prevalence of diabetes was significantly higher in lipodystrophic subjects than in non lipodystrophic subjects ($p < 0.001$, COR: 9.5, 95% CI: 2.975-30.119). This finding was non-significant for hypertension ($p = 0.401$, 175 COR: 1.6, 95% CI: 0.6-4.3).

In multivariate analysis adjusted for age and duration of HAART both lipoatrophy and lipohypertrophy were significantly associated with diabetes mellitus while only lipohypertrophy (adjusted for age) remained to be significantly associated with hypertension (Tables 3 and 4).

Table 3. Factors associated with diabetes mellitus in HAART receiving HIV patients, Sodo town, Southern Ethiopia, 2010

Subjects' characteristics		Total	Prevalence of DM (n %)	COR (CI)	AOR(95%CI)
Age, yr	< 40	128	4(2.3)	1	1
	≥40	48	10(5.7)	8.2(2.4-27.5)*	17.04(2.9-98.2)*
Sex	Male	86	2(1.1)	1	1
	Female	90	12(6.8)	6.5(1.4-29.8)*	18.3(2.5-136.2)*
Ethnicity	Wolayita	140	8(4.5)	1	
	Others	36	6(3.4)	3.3(1.1-10.2)*	
Income	< 600	148	8(4.5)	1	
	≥ 600	28	6(3.4)	4.8(1.5-15.1)*	
BMI baseline	Under weight	60	2(1.1)	1	
	Normal weight	110	6(3.4)	1.7(0.3-17.4)	
	Overweight and Obese	6	6(3.4)	-	
BMI recent	Under weight	26	2(1.1)	1	1
	Normal weight	136	2(1.1)	0.2(0.01-2.6)	-
	Overweight and Obese	14	10(5.7)	30(3.8-334)*	-
Work intensity	Much heavier	78	6(3.4)	1	
	As heavy	44	0(0)	0.0(0.0-1.5)	
	Much lighter	54	8(4.5)	2.1(0.6-7.8)	
Walking at leisure time	No		12(6.8)	1	1
	Yes		2(1.1)	0.13(0.01-0.6)*	-
HAART duration	< 4 yrs	136	2(1.1)	1	1
	≥ 4 yrs	40	12(6.8)	28.7(6.1-135.5)*	48.7(7.4-321.3)*
CD4 baseline	< 350	166	14(7.9)	1	
	≥350	10	0(0)	.916(0.8-1.0)	
CD4 recent	< 350	94	0(0)	1	
	≥350	82	14(7.9)	1.2(1.1-1.3)*	

**p = 0.05; DM: diabetes mellitus COR – crude odds ratio; AOR – adjusted odds ratio.*

Table 4. Factors associated with hypertension in HAART receiving HIV patients, Sodo town, Southern Ethiopia, 2010

Subjects' characteristics		Total	Prevalence of hypertension (n %)	COR(CI)	AOR(95%CI)
Number of subjects		176	28(15.9%)		
Age, yr	< 40	128	15(8.5)	1	1
	≥40	48	13(7.4)	2.8(1.2-6.4)*	3.0(1.3-6.9)*
Sex	Male	86	14(7.9)	1	
	Female	90	14(7.9)	.95(0.4-2.10)	
Ethnicity	Wolayita	140	21(11.9)	1	
	Others	36	7(4.0)	1.4(0.5-3.5)	
BMI baseline	Under weight	60	6(3.4)	1	
	Normal weight	110	22(12.5)	2.2(0.8-7.2)	
	Overweight and Obese	6	0(0.0)	0.0(0.0-9.8)	
BMI recent	Under weight	26	2(1.1)	0.4(0.05-2.0)	
	Normal weight	136	22(12.5)	1	
	Overweight and Obese	14	4(2.3)	2.1(0.4-8.0)	
Work intensity	Much heavier	78	16(9.1)	1	
	As heavy	44	4(2.3)	0.4(0.1-1.3)	
	Much lighter	54	8(4.5)	0.0(0.0-1.5)	
Income	< 600	148	24(13.6)	1	
	≥ 600	28	4(2.3)	.9(0.3-2.7)	
HAART duration	< 4 yrs	136	20(11.4)	1	
	≥4 yrs	40	8(4.5)	1.4(0.6-3.6)	
CD4 baseline	< 350	166	28(15.9)	1	
	≥350	10	0(0.0)	.8(0.8-0.9)*	-
CD4 recent	< 350	94	17(9.7)	1	
	≥ 350	82	11(6.2)	.7(0.3-1.6)	

**p = 0.05; COR – crude odds ratio; AOR – adjusted odds ratio.*

4. DISCUSSION

The estimated prevalence of diabetes mellitus in the present study was 8%. No similar study conducted in Ethiopia was available for possible comparison. A study conducted in Jimma town, Ethiopia in the general population revealed a low prevalence of diabetes mellitus [13]. In a report by Guaraldi and coworkers [14] diabetes was observed in 5.7% of the subjects. Similarly, the finding of low prevalence of diabetes mellitus in the present study was comparable to some reports [5].

A cross-sectional study conducted in consecutively selected (81% male, 19% female) Slovenian patients reported that 7% of HAART receiving HIV patients had diabetes mellitus [15]. A study conducted in Iran to estimate the prevalence of dyslipidemia and metabolic abnormalities in HIV patients revealed that fasting hyperglycemia (FBS ≥ 110 mg/dl) was noted in 11.6% of patients on treatment [16]. The difference could be attributed to the difference in the participant characteristics that influence these disease conditions (Behavioral, stage of HIV infection, drug-specific effects, gender etc).The prevalence of diabetes mellitus could also have been influenced by using a single fasting glucose

measurement which could have lead to overestimation of its incidence. If the glucose tolerance test had been conducted, lower incidence of diabetes mellitus based on postprandial blood glucose levels could have been probable. This is one of the possible limitations of this study.

There have been limited published data, to date, that investigated prevalence of hypertension in certain populations and in the general Ethiopian population. The finding from the present study showed that prevalence of hypertension was small when compared to findings from Italy [14] but higher than from the general Ethiopian population [17]. Different studies have reported that HIV patients are at a higher risk of becoming hypertensive than the general population [3,5].

4.1 Factors Associated with Diabetes Mellitus and Hypertension

4.1.1 Host factor

The present study revealed that being female and above 40 yrs of age remained to be predictors of diabetes mellitus, while only age predicted the development of hypertension. Other socio demographic and clinical characteristics did not have a significant association with either diabetes mellitus or hypertension. Since only 1% of the subjects smoked, association of this factor with diabetes mellitus or hypertension was not studied.

Save and his colleagues reported that alterations in glucose tolerance were more prevalent among patients who were of older age, had higher BMI and less prevalent among patients with higher CD4 cell counts [5].

4.1.2 Treatment factors

The association between type of HAART and incidence of diabetes mellitus or hypertension was not studied since this is beyond the scope of the present study. However, this study showed that subjects who were on HAART for longer duration ($\geq$4 yrs) remained to be at a significantly increased risk of developing diabetes mellitus. A report from Tomazic and coworkers showed that duration of HAART was associated with the metabolic syndrome [15]. A study from France reported that alterations in glucose tolerance were more prevalent among patients who had exposure to indinavir [5].

4.1.3 Lipodystrophy as a factor

This study revealed that lipodystrophic subjects had higher prevalence of diabetes mellitus than non lipodystrophic subjects. The prevalence of diabetes mellitus was 4.6% in lipodystrophic subjects. The phenotypes of lipodystrophy, lipohypertrophy and lipoatrophy were positively associated with diabetes mellitus, while only lipohypertrophy was associated with hypertension.

In another study, 7% of patients who had clinical evidence of fat redistribution syndrome had diabetes mellitus [18].

In the present study, it was observed that hypertension was not influenced by the presence or absence of overall lipodystrophy. The prevalence of hypertension in lipodystrophic subjects was 3.4% and 12.5% in non lipodystrophic subjects. One clinical trial conducted in Italy revealed that prevalence of systolic or diastolic hypertension was 19.8% at baseline in

consecutive lipodystrophic patients attending metabolic clinics [14]. The results of the present study revealed that lipohypertrophy predicts the presence of hypertension.

4.1.4 Prevalence of other risk factors of CVD

The participants of the present study were different in some health related behaviors from the participants of other studies. There were very little number of subjects (1 %) who smoked cigarettes or drank alcohol. The habit of regular physical activity was observed in 9.1% of subjects. In a study by Cheng and coworkers [19], where the effect of alcohol on lipodystrophy was examined, 66% of the participants reported at least one moderate to heavy alcohol drinking per day. Another study reported that 43.5% were smokers, 43.9% subjects were drinking alcohol at varying amounts and 37.7% of the subjects engaged in moderate to intense physical activity [14]. A study from Swiss HIV cohorts conducted to determine the prevalence of cardiovascular risk factors in HIV positive individuals revealed that more than 50% of HIV individuals were smokers [20].

A number of primary or traditional risk factors for CVD are well established, and several additional risk factors have been recently described. The primary risk factors for CVD in the general population include age, smoking, hypertension, elevated total and LDL cholesterol levels, diabetes mellitus, obesity and physical inactivity [21].

For HIV-infected patients receiving treatment with ART, the risk for CVD may be significantly greater than that for the general population and may increase with each year of ART exposure. Recent cohort and database studies suggest that cardiovascular events substantially contribute to mortality in HIV-infected patients receiving successful highly active antiretroviral therapy (HAART) [3].

5. CONCLUSION

Lipodystrophy syndrome has severe health consequences, as it may be responsible for stigma, reduced adherence to antiretroviral treatment and increased risk of cardiovascular diseases (CVD) [22]. Since lipoatrophy (adjusted for age and duration of HAART) was significantly associated with diabetes mellitus and lipohypertrophy (adjusted for age and duration of HAART) was associated with diabetes mellitus and (adjusted for age) was associated with hypertension, there is a need to investigate types of HAART regimens which do not lead to lipodystrophy and associated diabetes mellitus or hypertension in AIDS/HIV subjects. Also counseling of the subjects with respect to smoking, alcohol and physical activity may help to reduce the incidence of cardiovascular diseases in AIDS subjects in the long run.

CONSENT

All authors declare that ‘written informed consent was obtained from the patients (or other approved parties) for participation in the study.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the Hawassa University ethics committee and have therefore been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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