

Prevalence and predictors of dyslipidemia on HAART and HAART naive HIV positive clients attending Debre Tabor Hospital, Debre Tabor, Ethiopia

Anemut Tilahun Mulu (✉ anemuttilahun@gmail.com)

Debre Tabor University <https://orcid.org/0000-0003-0496-6884>

Getachew Yideg Yitbarek

Debre Tabor University

Fitalew Tadele Admasu

Debre Tabor University

Chalachew Yenew Denekew

Debre Tabor University

Biruk Demissie Melese

Debre Tabor University

Research

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Abstract

Background: HAART has been reported to be associated with a number of side effects in human immunodeficiency virus patients among which dyslipidemia is a common metabolic disorder.

Methods: A facility based comparative cross-sectional study among 228 HIV positive persons was conducted from July to August 2020. Socio-demographic and clinical data were collected using structured questionnaires. Fasting venous blood sample was drawn for Lipid profiles and CD4 cell determination. Anthropometric measurement was done. Data was analyzed using SPSS version 22 for windows. Result: A total of 228 HIV patients were enrolled in the study. Prevalence of dyslipidemia in HAART naïve and on HAART HIV positive persons was 61(53.5%) and 84 (73.7%), respectively. The prevalence of $TC \geq 200$ mg/dl was 50% and 30%; $HDL-c < 40$ mg/dl was 43.8% and 36%; $LDL-c \geq 130$ mg/dl was 48.3% and 28.1%; and $TG \geq 150$ mg/dl 59.6% and 39% among on HAART and HAART naïve, respectively. Age greater than 40 years (AOR = 3.27, 95% C.I: 1.47 - 7.25), blood pressure $\geq 140/90$ (AOR = 16.13, 95% C.I: 5.81 - 44.75), being on HAART (AOR = 2.73, 95 % C.I: 1.35 - 5.53) and body mass index > 25 kg/m² (AOR = 1.92, 95 % C.I: 1.20 - 4.81) were identified as determinants of dyslipidemia.

Conclusion: The mean value of lipid profile was significantly higher among HIV positive clients on HAART as compared to those HAART naïve HIV positive clients.

1. Background

Acquired Immune Deficiency Syndrome (AIDS) has become a global public health concern [1]. The different HAART regimens being used by many countries include a combination of at least three drugs such as protease inhibitors (PI), non-nucleoside reverse transcriptase inhibitors (NNRTI) and nucleoside reverse transcriptase inhibitors (NRTI)[1]. The introduction and extensive utilization of HAART in the treatment of HIV infection has led to significant reduction in AIDS-related morbidity and mortality[2].

Nowadays the World Health Organization (WHO) recommends the combination of two NRTI with a NNRTI [3]. PIs have become compulsory component of second-line treatment subsequent to failure of first-line regimens in which a change from Tenofovir/Lamivudine/Efavirenz (TDF/3TC/EFV) preferred first line combination to Tenofovir/Lamivudine/Lopinavir/r (TDF/3TC/LPV/r) second line combination [3]. Despite the pivotal role of HAART in the treatment of HIV infection, the use of HAART is reported to be associated with a series of side effects in HIV/AIDS infected clients [4]. The use of HAART is associated with abnormal changes in lipid profile in PLHIV [5]. Some of the lipid abnormalities include; elevated level of total cholesterol (TC), low-density lipoprotein-cholesterol (LDL-c), triglyceride (TG) and decreased level of high-density lipoprotein-cholesterol (HDL-c) [3]. Use of stavudine (d4T) and PIs have been reported to cause an elevation of the blood levels of TC, LDL-c, and TGs with variable effects on levels of HDL-c [6]. Use of Nevirapine has been associated with increased LDL-c, whereas use of long term use of efavirenz for long period of time has been associated with increase TC and TG[7].

Mechanism for the development of lipid abnormality is still unclear and proposed to be multi factorial[8]. The individual contributions of HIV infection, specific ARV agents, host genetics and changes in body composition all should be considered for the development of lipid abnormality among PLHIV [9]. These high levels of lipids increase the likelihood of developing blood clots, heart disease and heart attack, stroke and pancreatitis [1].

Most deaths among HIV positive clients are from liver disease, kidney disease and cardiovascular complications with factors related to the virus, the host and ART factors[10]. All HIV patients with dyslipidemia may not require lipid lowering therapy. The goal of lipid lowering therapy is to minimize an individual's cardiovascular risk. So, treatment of HIV-associated dyslipidemia should be a component of an attempt to improve cardiovascular health. Continuous monitoring and advice on diet and exercise, smoking cessation, management of hypertension and diabetes if present and use of anti-platelet agents are crucial measures in managing HIV associated dyslipidemia [11].

Although WHO ART guidelines do not include lipid monitoring in HIV treatment, lipid monitoring should be included in patients receiving HAART [4]. The prevalence of dyslipidemia on HAART individuals in resource-limited settings also has not been well characterized[12]. This study was aimed at identifying risk factors of dyslipidemia in HIV patients and determining whether HIV patients on HAART have high level of dyslipidemia compared to HAART naïve HIV positive clients [13].

2. Methodology

2.1. Study Area and Period

A facility based cross-sectional study was conducted in Debre Tabor Referral Hospital from July to August 2020.

2.2. Sample Size and Study Subjects

The sample size was determined using two population proportion formula by considering the following assumptions: proportion of HIV positive persons on HAART with LDL-c \geq 130 (40.8%) [3]and proportion of HIV positive persons naïve for HAART with LDL-c \geq 130 (21%) [11]. Level of significance ($\alpha/2$) = 5%; power ($1 - \beta$) = 90%; r = (Ratio of exposed: none exposed) = 1:1. By adding 10% non-response rate the final sample size was 228 (114 on HAART and 114 HAART naïve HIV positive clients).

All HIV positive persons (age \geq 18 years) who were available during the study period were included. HIV patients with known DM, renal failure and on anti TB drugs were excluded from the study. HIV positive persons on HAART who change their regimen in less than a year and who took HAART for less than a year were excluded from the study.

2.3. Data Collection Techniques and Instruments

One BSc-nurse for socio-demographic data collection and two laboratory technologists for laboratory analysis were assigned throughout the data collection period. Structured questionnaire was used for socio-demographic data collection. Anthropometric measurements, height and weight were done.

2.4. Blood Specimen Processing and Analysis

A fasting venous blood sample was drawn for lipid profile and CD4 cell determination in separate test tube using vacutainer blood collection system. EDTA anti-coagulated venous blood was processed for CD4 count using BD FACS Count™ (BD USA). The TC/HDL-c ratio was also calculated. Lipid profile was assessed through enzymatic Methods using Clinical chemistry Analyzer (HumStar80, Canada).

According to the US National Cholesterol Education Program, Adult Treatment Panel III (NCEP-ATP III) guidelines, abnormal lipid profile was defined as TC \geq 200 mg/dl, HDL-c $<$ 40mg/dl, LDL-c \geq 130 mg/dl, TG \geq 150mg/dl, TC/HDL-c ratio \geq 5 [8]. An elevation of any one of the lipid parameters above these limits was considered as dyslipidemia [7].

2.5. Data Quality Assurance

Questionnaire was translated to the local Amharic language and the Amharic version was used for the interview. Weight measurement was done using a digital scale to the nearest 0.1 kg. A fixed base calibrated height scale was used for height measurement to the nearest 0.1 cm. Measurements were done twice and the mean values were used to compute BMI. All reagents were checked for expiry date.

2.6. Statistical Analysis

Data was coded and entered using Epi-Info version 3.5.6 and then exported to SPSS version 22 for analysis. Descriptive statistics using frequency distribution was done for socio-demographic and clinical characteristics of study participants. Binary and multivariate logistic regression and independent student's T-test were done. A P value $<$ 0.05 were considered as statistically significant.

3. Results

3.1. Socio-demographic and Characteristics of Study Participants

A total of 228 HIV positive persons were enrolled in this study from whom, majority, 125 (54.82 %) were females. Majority of study participants were within the age group of 31–40 years. The mean age of study participants was 35.31 (\pm 7.20). The majority of patients can read and write.

Majority (61.4%) of the patients are urban residents. 29 (12.8%) of the patients had smoking history (Table 1).

Table 1
Socio-demographic characteristics of HIV patients on HAART and
HAART naïve in Debre Tabor referral hospital, Debre Tabor, Ethiopia,
2020.

| Variable | Categories | On HAART | HAART naïve |
|--------------------|-----------------|----------|-------------|
| Sex | Male | 53 | 50 |
| | Female | 61 | 64 |
| Age | 18–30 | 24 | 32 |
| | 31–40 | 67 | 62 |
| | > 40 | 31 | 20 |
| Educational status | Illiterate | 15 | 19 |
| | Read and write | 69 | 70 |
| | Diploma & above | 30 | 25 |
| Residence | Rural | 46 | 42 |
| | Urban | 68 | 72 |
| Smoking habit | Yes | 17 | 12 |
| | No | 97 | 102 |
| Physical exercise | Yes | 39 | 42 |
| | No | 75 | 72 |

3.2 Clinical characteristics of study participants

49 (21.5%) of the study participants were obese. 99 (43.4%) of the study participants were hypertensive. 68 (29.8%) of the participants have a CD4 count of < 350 cells/mm³, while 103 (45.2%) have a CD4 count of 350–550 cells/mm³ and 57 (25%) of the participants have a CD4 count of > 550 cells/mm³ (Table 2).

Table 2
clinical parameters of HIV patients on HAART and HAART naïve in Debre Tabor referral hospital, Debre Tabor, Ethiopia, 2020.

| Variable | Categories | On HAART | HAART naïve |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|----------|-------------|
| BMI (Kg/m ²) | < 18.5 | 5 | 9 |
| | 18.5–25 | 78 | 87 |
| | > 25 | 31 | 18 |
| Blood pressure (MmHg) | < 140/90 | 61 | 68 |
| | ≥ 140/90 | 53 | 46 |
| CD4 cells/mm ³ | < 350 | 19 | 49 |
| | 350–550 | 52 | 51 |
| | > 550 | 43 | 14 |
| <p>N.B: HAART = highly active antiretroviral therapy, No = Number, BMI = Body Mass Index, Kg/m² = Kilo gram per Meter square, *blood pressure as systolic/diastolic, ZDV = Zidovudine, 3TC = Lamivudine, EFV = Efavirenz, NVP = Neverapine, TDF = Tenofovir, LPV/r = Lopinavir/r</p> | | | |

3.3 Lipid Profile of study participants

Majority (63.6%) of the study participants have dyslipidemia. 91(39.9%) of the study participants have a total cholesterol of ≥ 200mg/dl. 91 (39.9%) of study participants have diminished level of HDL-c (< 40 mg/dl). 87(38.1%) of the study participants have elevated level of LDL-c (> 130 mg/dl). 112 (49.1%) of the study participants have elevated level of TG (> 150 mg/dl) (Table 3).

Table 3
Serum lipid profile of study population by HAART status in Debre Tabor referral Hospital, Debre Tabor -Ethiopia from July 20 to August 13, 2020.

| Variable | Categories | On HAART No (%) | HAART naïve No (%) |
|--------------------|-------------|-----------------|--------------------|
| Total dyslipidemia | Absent | 30 (26.3) | 53 (46.5) |
| | Present | 84 (73.7) | 61 (53.5) |
| TC | < 200 mg/dl | 57 (50) | 80 (70.2) |
| | ≥ 200mg/dl | 57 (50) | 34 (29.8) |
| HDL-c | < 40 mg/dl | 50 (43.85) | 41 (36) |
| | ≥ 40 mg/dl | 64 (56.15) | 73 (64) |
| LDL-c | < 130 mg/dl | 59 (51.75) | 82 (71.9) |
| | ≥ 130 mg/dl | 55 (48.25) | 32 (28.1) |
| TG | < 150 mg/dl | 46 (40.4) | 70 (61.4) |
| | ≥ 150 mg/dl | 68 (59.6) | 44 (38.6) |

N.B: NO = Number, HAART = highly active antiretroviral therapy, TC = total cholesterol, HDL-c = High-Density Lipoprotein-cholesterol, LDL-c = Low-Density Lipoprotein-cholesterol, TG = triglyceride, TC/HDL-c ratio = total cholesterol/High-Density Lipoprotein-cholesterol ratio

3.4. Associated Risk Factors of Dyslipidemia

Among the study participants involved, 84 (73.68%) on HAART and 61 (53.51%) HAART naïve persons had at least one lipid abnormality. The prevalence of dyslipidemia on HAART for TC, LDL-c & TG was greater than HAART naïve which was significantly different. The Mean value of TC, LDL-c and TG were higher in persons on HAART than in HAART-naïve whereas the mean value of HDL-c was higher among HAART-naïve than on HAART HIV positive persons (Table 3 &4).

Table 4. Comparison of the mean of variables by HAART status at Debre Tabor Hospital, Debre Tabor -Ethiopia from July 20 to August 13, 2020.

| Variable | Group | Mean (SD) | t (95% CI) | P-value |
|---------------------------|-------------|----------------|----------------------|---------|
| Age in years | HAART naïve | 34.42 (6.49) | | |
| | On HAART | 36.3 (7.81) | 1.9(0.01, 3.74) | 0.318 |
| TC | HAART naïve | 186 (24.09) | | |
| | On HAART | 202 (23.98) | 4.9(9.41, 21.88) | <0.001 |
| HDL-c | HAART naïve | 43.85 (7.91) | | |
| | On HAART | 40.52 (6.09) | -3.49 (-5.18, -1.53) | <0.001 |
| LDL-c | HAART naïve | 111.35 (24.79) | | |
| | On HAART | 126 (22.86) | 4.6(8.84, 19.81) | <0.001 |
| TG | HAART naïve | 155 (23.34) | | |
| | On HAART | 175 (36.81) | 5.11 (11.90, 28.16) | <0.001 |
| CD4 Cells/mm ³ | HAART naïve | 339 (75.88) | | |
| | On HAART | 500 (157.25) | 9.9(128.55, 193.13) | <0.001 |
| BMI in kg/m ² | HAART naïve | 22.11 (2.63) | | |
| | On HAART | 23.33 (2.72) | 3.4(0.54, 1.92) | 0.862 |

Multivariable logistic regression analysis was done for variables having $p < 0.25$ in binary logistic regression analysis (Age, CD4 count, BMI, blood pressure, and HAART status). After controlling potential confounding factors in multiple logistic regression analysis; age greater than 40 years old (AOR = 3.27, 95% C.I: 1.47–7.25), blood pressure $\geq 140/90$ (AOR = 16.13, 95% C.I: 5.81–44.75), being on HAART (AOR = 2.73, 95 % C.I: 1.35–5.53) and body mass index $> 25\text{kg}/\text{m}^2$ (AOR = 1.92, 95 % C.I: 1.20–4.81) were identified as determinants of Dyslipidemia (Table 5).

Table 5. Associations of variables with dyslipidemia among persons on HAART and HAART naïve in Debre Tabor Hospital, Debre Tabor -Ethiopia from July 20 to August 13, 2020
Outcome variables in mg/dl (95 % CI)

| Explanatory Variable | | | | | |
|--------------------------|---------|--------------------|------------------|-------------------|-------------------|
| | | TC ≥ 200 | HDL-c < 40 | LDL-c ≥ 130 | TG ≥ 150 |
| Male | COR | 1.01(0.58-1.72) | 1.6(0.57-1.63) | 1.10(0.65-1.92) | 1.23(0.71-2.01) |
| | P-value | 0.990 | 0.880 | 0.720 | 0.510 |
| Age>40 years | COR | 4.88 (2.05-11.61) | 4.32(1.12-16.54) | 4.05(1.77-9.27) | 9.20(2.39-35.49) |
| | P-value | 0.001 | 0.030 | 0.001 | <0.001 |
| CD4 <350 cells/mm3 | COR | 3.31(1.50-7.28) | 2.06(0.96-4.44) | 4.00(1.80-8.87) | 3.39(1.52-7.58) |
| | P | 0.003 | 0.062 | 0.001 | 0.003 |
| BMI>25kg/m2 | COR | 2.01(1.34-6.15) | 5.22(2.63-10.72) | 3.20(1.71-7.55) | 10.83(1.38-84.37) |
| | P-value | <0.011 | <0.001 | <0.001 | <0.001 |
| On HAART | COR | 2.34(1.36-4.02) | 1.44(0.85-2.41) | 2.46(1.42-4.23) | 2.53(1.49-4.31) |
| | P-value | 0.002 | 0.180 | 0.001 | <0.001 |
| Blood pressure ≥140 /90* | COR | 25.32(12.43-51.59) | 8.01(4.40-14.57) | 16.87(8.62-33.01) | 9.44(5.12-17.41) |
| | P-value | <0.001 | <0.001 | <0.001 | <0.001 |

N.B: COR = Crude Odds Ratio, CI = Confidence Interval, TC = total cholesterol, HDL-c = High-Density Lipoprotein-cholesterol, LDL-c = Low-Density Lipoprotein-cholesterol, TG = triglyceride, BMI = Body Mass Index, HAART = highly active antiretroviral therapy, *blood pressure as systolic/diastolic

Table 6. Determinant factors of Dyslipidemia and lipid profile level among HIV positive persons, adjusted for the potential confounding factors of study participants in Debre Tabor Hospital, Debre Tabor -Ethiopia from July 20 to August 13, 2020

| Explanatory Variable | lipid profile level in mg/dl (95 % CI) | | | | |
|-------------------------|----------------------------------------|--------------------|------------------|-------------------|-------------------|
| | Dyslipidemia | TC ≥ 200 | HDL-c < 40 | LDL-c ≥ 130 | TG ≥ 150 |
| Age>40 years old | AOR 3.27(1.47-7.25) | | | | 2.44(1.06-5.64) |
| | P-value 0.004 | | | | 0.037 |
| BMI>25kg/m2 | AOR 1.92(1.20-4.81) | 2.31(1.04-7.66) | | 3.20(1.71-7.55) | 10.83(1.38-84.37) |
| | P-value 0.044 | 0.025 | | <0.001 | <0.001 |
| On HAART | AOR 2.73(1.35-5.53) | 3.15(1.49-6.68) | | 3.02(1.42-4.23) | 2.87(1.51-5.45) |
| | P-value 0.005 | 0.003 | | 0.002 | 0.001 |
| Blood pressure ≥140 /90 | AOR 16.13(5.81-44.75) | 28.59(13.39-61.04) | 5.24(2.69-10.22) | 18.44(9.10-37.41) | 7.08(3.45-14.53) |
| | P-value <0.001 | <0.001 | <0.001 | <0.001 | <0.001 |

N.B: AOR = Adjusted Odds Ratio, CI = Confidence Interval, TC = total cholesterol, HDL-c = High-Density Lipoprotein-cholesterol, LDL-c = Low-Density Lipoprotein

4. Discussion

The prevalence of dyslipidemia in this study was 145 (63.60%), of them 84 (73.68%) were on HAART and 61 (53.51%) were HAART naïve HIV positive clients. The mean value of TC, LDL-c and TG were higher in HIV clients on HAART than those who are not on HAART. The mean value of HDL-c was higher among HAART-naïve HIV clients than those on HAART. In this study the mean value of CD4 cell count on HAART group was significantly different from the HAART naïve HIV positive clients. But, CD4 cell count was not significantly associated with dyslipidemia and lipid profile level. This might be due to HAART effect on improving immunological status of HIV clients [14].

In this study the mean value of each lipid profile was significantly higher among HIV clients on HAART than HAART naïve HIV clients which was similar with a study conducted in Sao Paulo, Brazil[15]. In this study we found that the proportions of raised TC, LDL-c, TG and TC/HDL-c ratio were significantly higher among HIV clients on HAART when compared to HAART naïve HIV clients which indicates the atherogenic effect of HAART for the development of cardiovascular diseases[16]. The association between HAART

and adverse lipid profile has been largely described for regimens when hypothetically switching patients from first-line to second-line treatment [17].

HIV patients on HAART with TC \geq 200mg/dl (50%) was higher than the findings reported from; Cameron (37.7%), Hawassa-Ethiopia (43.4%) & Jimma-Ethiopia (6.4%) [3]. This variation might be due to the sampling technique and the cut of value used. A prospective study conducted in India for the effects of NNRTIs indicated that the proportion of patients with TC \geq 200mg/dl had increased from 1–26% after 12 month of treatment [18].

The prevalence of HDL-c $<$ 40mg/dl among HIV clients on HAART was 43.8%. This is comparable with the prevalence reported from Hawassa-Ethiopia which is 43.4% [3]. However, the prevalence of HDL-c $<$ 40mg/dl among HIV clients on HAART is higher than the prevalence reported from Jimma-Ethiopia (32.6%)[11]. The prevalence of LDL-c \geq 150mg/dl in our HAART group was 48.3% which is comparable with the prevalence reported from Cameron (46.4%) [17]. The prevalence of raised TG on HAART group was 59.6%, which is comparable with the report from Hawassa-Ethiopia (55.8%) But was higher than studies done in; India, Cameron, Jimma-Ethiopia reported 32%, 39%, 18.2%, respectively[3, 11]. This might be due to difference in magnitude of lipid profile derangements induced by HAART with duration of treatment, across populations and setting.

5. Conclusion

The raised levels of TC, LDL-c and TG values were significantly associated with utilization of HAART regimens. The mean value of all lipid parameters was significantly higher among HIV clients using HAART when compared to those HIV clients who do not use HAART regimens. Old age, raised BP, being on HAART and increased in BMI were determinant factors of dyslipidemia among HIV clients. So, further studies with long term follow-up are vital to explain more on the causes of dyslipidemia and the pattern of lipid profile changes with HAART in HIV clients in resource limited countries.

Abbreviations

ARV- Anti-Retro-Viral

CART- Combined anti-retroviral therapy

HAART- Highly Active Anti-Retroviral Therapy

HDL- High Density Lipoprotein

HIV- Human Immune-Deficiency Virus

LDL- Low Density Lipoprotein

NNRTI- Non-Nucleoside Reverse Transcriptase Inhibitors

NRTI- Nucleoside Reverse Transcriptase Inhibitors

PI- Protease Inhibitor

TC- Total Cholesterol

TG- Triglycerides

WHO- World Health Organization

Declarations

Data Availability

The SPSS data used to support the findings of this study are available from the corresponding author upon request.

Consent to publish

Not applicable

Ethical approval

Ethical approval was obtained from Debre Tabor University Ethical Review Board and a letter of permission to conduct the study was obtained from Debre Tabor Hospital clinical director office. Written informed consent was obtained from each study participants

Conflict of interest

The authors declare that they have no competing interests.

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Author's contributions

Anemut- perform data entry, analysis and interpretation.

Getachew- perform the statistical analysis and data interpretation in collaboration with Anemut.

Fitalew- accomplishes the manuscript write up.

Chalachew- participates in write up

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