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Posted Date: 13 April 2026

doi: 10.20944/preprints202604.0794.v1

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Article

# Prevalence of Lipid Profile Alterations Among Patients Receiving HAART in Selected Primary Healthcare Facilities

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## Abstract

**Background:** Highly active antiretroviral therapy (HAART) has transformed HIV into a manageable chronic condition but is associated with dyslipidaemia, increasing cardiovascular disease (CVD) risk. Data on lipid profile alterations in rural South Africa primary healthcare settings remain limited despite high HIV burdens. The purpose of the study was to determine the prevalence of lipid profile alterations among adult HIV patients receiving HAART at rural Eastern Cape primary healthcare facilities. **Methods:** Retrospective cross-sectional analysis of clinical and laboratory records from 370 adults (>18 years) on HAART at five OR Tambo District health care facilities (2020 – 2024) Lipid parameters (Total cholesterol {TC} LDL Cholesterol< HDL cholesterol, Triglycerides {TG} from National Health Laboratory Services (NHLS) data base were assessed NCRP ATP III thresholds. Prevalence was calculated with SPSS v29.0; overall dyslipidaemia defines as any abnormality. **Results:** High prevalence of lipid alterations was observed: hypercholesterolemia 53.8% (199/370). Overall dyslipidaemia affected 80.8% (299/370) of patients, confirming substantial metabolic burden in this rural cohort. **Conclusion:** Over 80% of rural HAART patients exhibited dyslipidaemia predominantly elevated LDL-cholesterol, LDL+C (61.4%) and triglycerides (60.5%) Findings underscore urgent need for routine lipid screening, regimen optimisation toward integrase strand transfer inhibitors. (INSTIs) and NCD-HIV integration in South Africa's primary healthcare system to mitigate CVD risk.

**Keywords:** HIV; HAART; dyslipidaemia; lipid profile; primary healthcare; Eastern Cape; South Africa

## 1. Introduction

Human immunodeficiency Virus (HIV) infection remains one of the most significant global public health challenges, with an estimated 40.8 million [37.0-45.6 million] people living with HIV worldwide as of 2024, of whom 1.4 million [1.1-1.8] are children (0-14 years old) and 39.4 million adults (15+ years old) [1]. In sub-Saharan Africa, which bears approximately 65% of the global HIV burden, South Africa stands has the highest number of infections, with about over 8.0 million people living with HIV representing about 12.7% of the total population [2]. The Eastern Cape Province, including East London, exemplified this regional strain, where HIV prevalence among adults aged 15-49 years hovers around 20-25%, driven by factors such as socioeconomic disparities, limited healthcare access, and high rates of undiagnosed cases [3].

The advent of Highly Active Antiretroviral Therapy (HAART), now more commonly referred to as Antiretrovirals Therapy (ART), has revolutionized HIV management since its introduction in mid-1990s. HAART regimens, typically comprising combinations of nucleotide reverse transcriptase

inhibitors (NRTIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs), protease inhibitors (Pi's) and integrase strand transfer inhibitors (INSTIs), suppress viral replication, restore immune function, and transform HIV from a fatal disease into a manageable chronic condition [4]. In South Africa, nationwide ART rollout began in 2004 under the public health system, achieving remarkable scale-up by 2025, over 5.5 million people were on treatment, with viral suppression rates exceeding 90% in adherent populations. Primary Healthcare Facilities (PHCFs) serve as the frontline for this delivery, particularly in resource-limited settings, where task-shifting to nurses and community health workers has decentralized care and improved retention [5].

Despite these successes, HAART is associated with metabolic complications, notably alterations in lipid profiles collectively termed dyslipidaemia. Lipid profile alterations encompass elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), triglycerides (TG), and reduced high-density lipoprotein cholesterol (HDL-C), which collectively heighten cardiovascular disease (CVD) risk [6]. HIV itself contributes to dyslipidaemia: for example, the HIV accessory protein Vpr can inhibit intracellular peroxisome-proliferator-activated receptor gamma (PPAR- $\gamma$ ), leading to free fatty acid (FFA) overaccumulation and lipotoxicity [5]. HIV Nef protein was identified to impair cholesterol efflux from infected macrophages by affecting ATP-binding cassette transporter protein A1 (ABCA1) function, which ultimately leads to circulating high-density lipoprotein cholesterol (HDL-C) deficiency.[5] Additionally, HIV Tat protein promotes the up-regulation of cholesterol biosynthesis genes, leading to elevated free cholesterol cholesteryl esters levels. through chronic inflammation, immune activation, and opportunistic infections, but HAART exacerbates this via direct drug effects. Protease inhibitors (e.g., Lopinavir/ ritonavir) inhibit lipolysis and promote lipogenesis, leading to hypertriglyceridemia and low HDL-C. NNRTIs like efavirenz increase TC and LDL-C, while some NRTIs (e.g., stavudine, zidovudine) induce mitochondrial toxicity, fat redistribution (lipoatrophy), and insulin resistance. Newer regimens with dolutegravir-based INSTIs show improved profiles but still pose risks, particularly in polypharmacy scenarios common in PHCFs [7].

## 2. Materials and Methods

### 2.1. Study Design

This is a retrospective cross-sectional analytical study which utilized previously collected clinical and laboratory data from adult HIV-positive patients receiving Highly Active Antiretroviral Therapy (HAART) at selected rural primary healthcare facilities in the Eastern Cape province, South Africa, conducted under the Research Capacity Development initiative (RCDI) of the South African Medical Research Council (SAMRC)

### 2.2. Study Setting

Data were sourced from institutional clinical records and the National Health Laboratory Service (NHLS) database at five rural primary healthcare facilities in the OR Tambo District Municipality, Eastern Cape. These facilities provide comprehensive HIV care, including routine monitoring and laboratory investigations, serving predominantly rural communities with high HIV burdens (prevalence- 25% among adults aged 15-49%) [14]. The region features limited healthcare resources and high rates of comorbidities like tuberculosis, making it ideal for examining HAART-associated metabolic complications. Map of OR Tambo showing the five sub-municipalities [14].

### 2.3. Study Population

The study population was part of the primary Research Capacity Development Initiative South African Research Council (RCDI SAMRC, No (MRC-RFA-CC 01-2014) study that focused on black Africans in rural and urban selected healthcare facilities in O.R Tambo District Municipality, Eastern Cape.

#### 2.4. Inclusion Criteria

- Adults aged  $\leq 18$  years old
- Individuals without HIV diagnosis or not on HAART.

#### 2.5. Excluding Criteria

- Adults aged  $\geq 18$  years diagnosed with HIV and receiving HAART at the selected facilities.

#### 2.6. Sampling Size and Sampling Strategy

##### 2.6.1. Sampling Strategy

A complete enumeration (Census) approach was used, including all eligible patients from the secondary dataset meeting inclusion criteria.

##### 2.6.2. Sample Size Calculation

Sample size was calculated using formula for estimating population proportion:

$$N = \frac{Z^2 P(1-p)}{d^2}$$

where  $Z= 1.96$  (95% confident level),  $P=0.75$  (expected dyslipidaemia prevalence based on prior studies: 70-80%), and  $d=0.05$  (precision). This yielded  $n=289$ , adjusted to 318 for a 10% non-response rate. Complete data were available for 370 participants, all included to enhance statistical power.

#### 2.7. Statistical Analysis

Analysis was performed using SPSS version 29.0. Descriptive statistics included frequencies/percentages for categorical variables and means  $\pm$  standard deviations for continuous variables. For HAART regimen comparisons, one-way ANOVA assessed mean lipid level differences (post-hoc Tukey test for pairwise comparisons).

##### 2.7. Patients Records Review for Clinical Data Collection

Clinical data were collected through retrospective review of patient's medical records at selected rural primary healthcare facilities in the Eastern Cape province. Trained research assistants extracted information from paper-based and/ or electronic patient files, ART registers, and laboratory result sheets using a standardized data collection form aligned with the study variables. The form captured demographic characteristics (age, sex, education), HIV-related factors (date of diagnosis, CD4 count, viral load, WHO clinical stage), HAART details (regimen type, start date, duration on treatment), comorbidities (Hypertension, diabetes), and lipid-related data (total cholesterol, LDL-C, HDL-C, triglyceride, and date of lipid profile). To minimize bias and errors, a pilot review of 10-20 records was conducted to refine form, and double-data entry and regular checks were performed to ensure accuracy and completeness of the extracted information.

#### 2.8. Specimen Collection, Storage, Transport, and Handling

Data were retrospectively extracted from clinical records and NHLS testing. Venous blood was collected into serum separator tubes, allowing to clot, centrifuged, and analysed on automated clinical chemistry analyzers (Roche Cobas) per manufacturer protocols. Parameters included TC, TG, HDL-C (direct assay), and LDL-C (calculated via Friedewald equation:  $LDL-C=TC-HDL-C - TG/2.2$ , valid if  $TG < 4.5$  mmol/L. all labs were NHLS-accredited with internal quality controls and external proficiency testing. Dyslipidaemia thresholds followed NCEP ATP III guidelines:  $TC \geq 5.3$  mmol/L,  $TG \geq 1.7$  mmol/L,  $HDL-C < 1.0$  mmol/L (men)/  $< 1.3$  mmol/l (women),  $LDL-C \geq 3.4$  mmol/L.

### 2.9. Laboratory Procedure (Serum Lipid Profile)

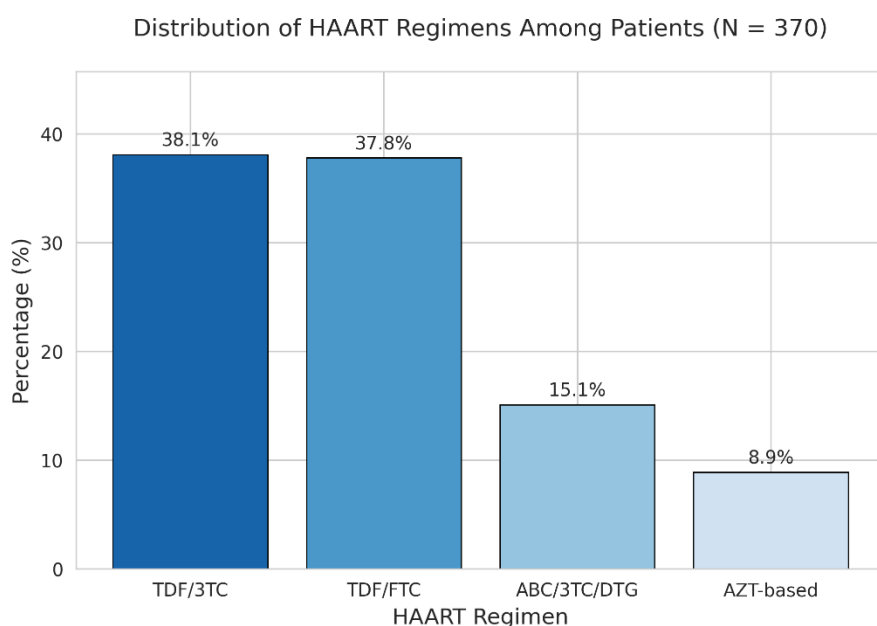
Lipid profile parameters were measured using serum samples obtained from fasting blood draws, as serum is generally preferred over plasma for lipid assays to avoid potential interferences from anticoagulants of lipids by interfering with enzymatic or colorimetric reactions, leading to inaccurate reporting of total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), and triglycerides (TG). To minimize such interference, samples were allowed to clot fully before centrifugation, and serum was separated promptly for analysis.

Lipid parameters were analyzed using standard enzymatic colorimetric methods on an automated clinical chemistry analyzer (e.g., Abbot ARCHITECT, Cobas, or similar), as routinely performed in clinical laboratories. Total cholesterol and triglycerides were measured via enzymatic reactions involving cholesterol esterase/ cholesterol oxidase and glycerol-3-phosphate oxidase/ peroxidase systems, respectively, producing a colored product whose absorbance is proportional to the analyte concentration, HDL-C was measured after selective precipitation of apolipoprotein-B containing lipoproteins, while LDL-C was either directly assayed using homogenous enzymatic methods or calculated using the Friedewald equation where triglyceride levels were below the recommended threshold. Assays were calibrated daily using manufacturer-recommended calibrators, and internal quality-control samples were run with each batch to ensure accuracy and precision of the lipid profile results.

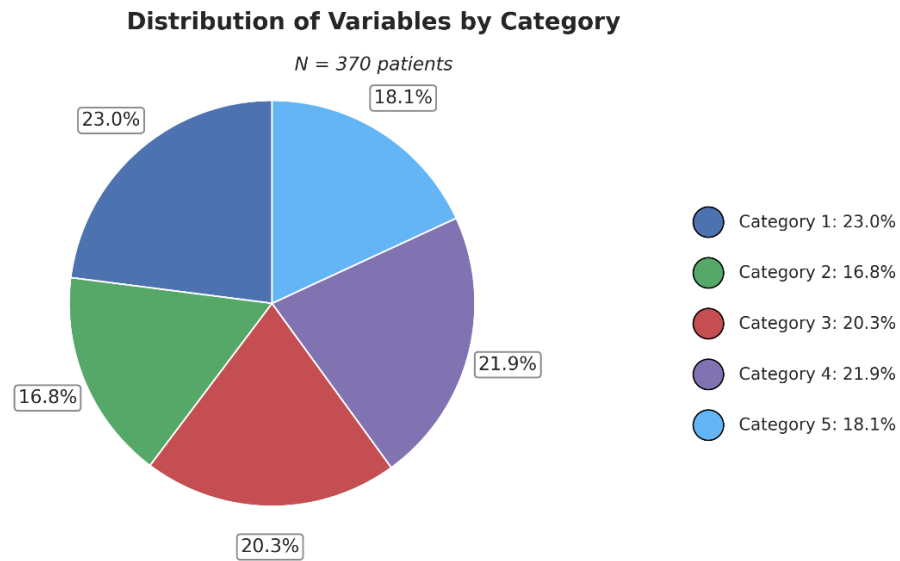
### 2.8. Ethical Considerations and Data Protection

Ethical approval was granted by Walter Sisulu University Faculty Research Ethics Committee (protocol: WSU HREC 461/2025), Data were anonymized (no personal identifiers retained), stored on password-protected laptop in Microsoft Excel, then exported to SPSS. Access was limited to the principal investigator and supervisors, ensuring confidentiality per POPIA and Helsinki Declaration Principles.

## 3. Results

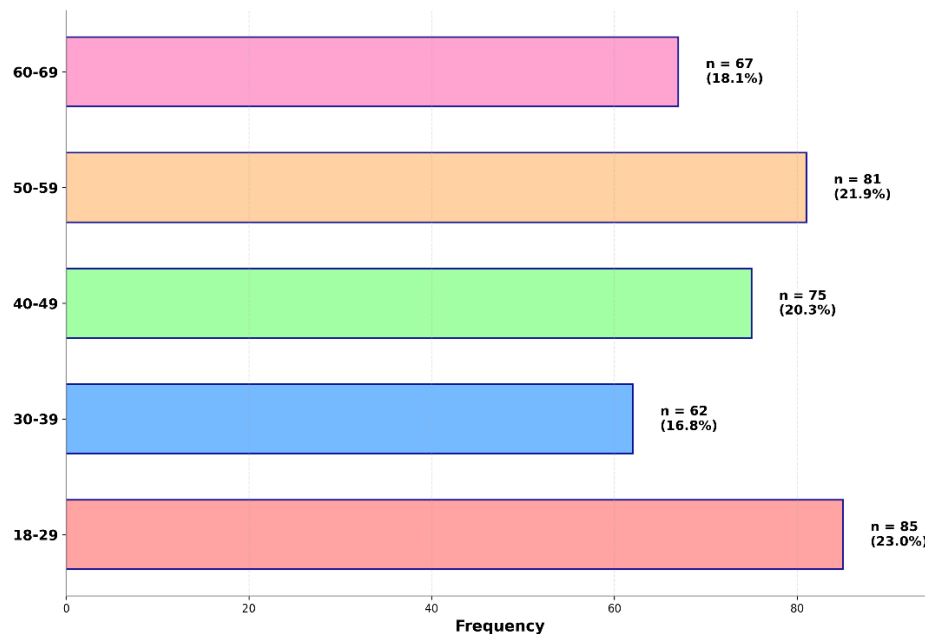


**Figure 3. 1:** Shows the distribution of participants according to HAART regimen. Majority participants were receiving TDF/3TC (38.1%, n=141) and TDF/FTC (37.8%, n=140). A smaller proportion were on ABC/3TC/DTG (15.1%, n=56), while the least represented regimen was AZT (8.9%, n=33).

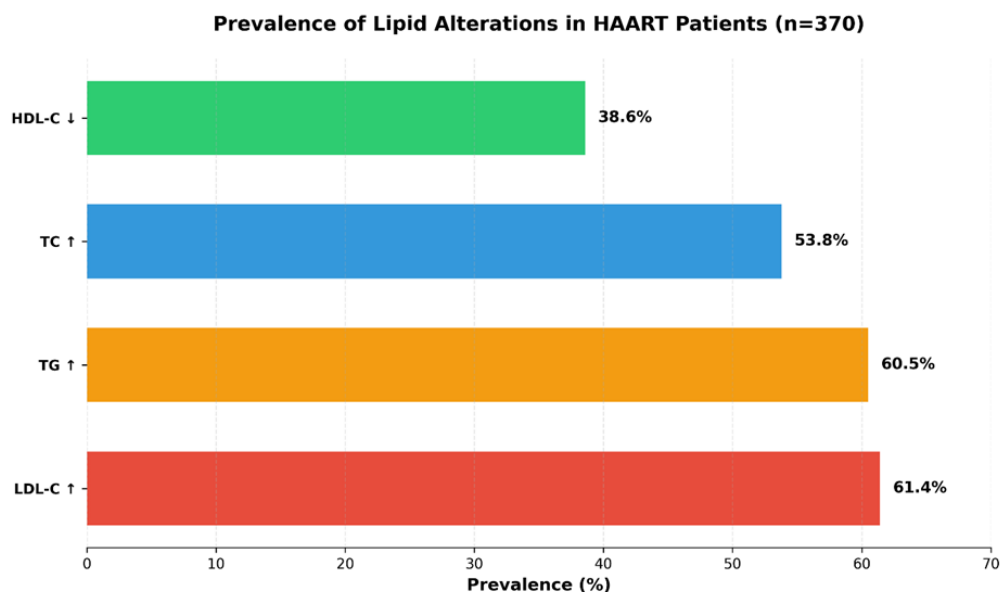


**Figure 3. 2:** Age category distribution among 370 adults HIV-positive patients receiving HAART at selected Eastern Cape primary healthcare facilities. Age categories: 1=18-29 years (23.0%), 2=30-39 years (16.8%), 3= 40-49 years (20.3%), 4= 50-59 years (21.9%), 5= ≥60 years (18.1%). The largest proportion of patients were in the 18-29 years (23.0%) and 50-59 years (21.9%) age groups.

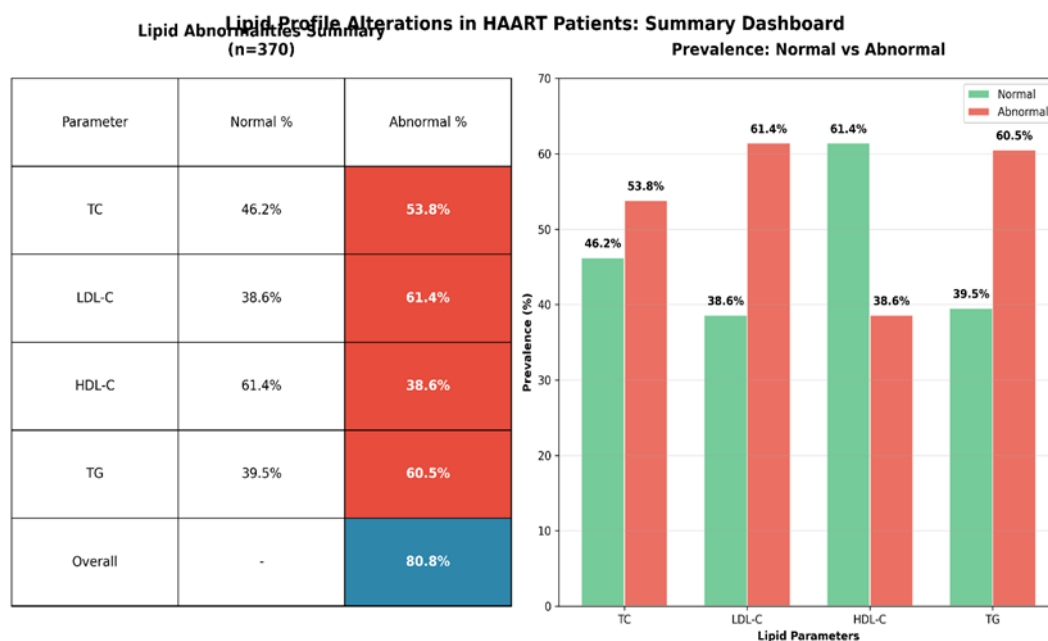
### Age distribution



**Figure 3. 3:** Age distribution of participants (n=370). The largest proportion fell within 18-29 years ( 23.0%, n=85), followed by 50-59 years (21.9%, n=81) and 40-49 years (23.3%, n=75), with 60-69 years (18.1%, n=67) and 30-39 years (16.8%, n=62) completing the distribution across five age categories.



**Figure 3. 4:** Bar chart showing prevalence of individual lipid abnormalities. This figure summarizes lipid profile alterations among 370 HAART patients. Hypercholesteremia affected 53.8% (n=199), elevated LDL-C 61.4% (n=227), low HDL-C 38.6% (n=143), and hypertriglyceridemia 60.5% (n=224). Overall, 80.8% exhibit at least one lipid abnormality, confirming high dyslipidaemia burden in this rural cohort.



**Figure 3. 5:** Dual-panel visualization of lipid abnormalities among 370 adult patients receiving HAART at rural Eastern Cape primary health care facilities. Left panel: summary table showing prevalence of normal vs abnormal parameters (red highlighting indicates abnormal rates). Right Panel: Grouped bar chart comparing normal (green) versus abnormal (red) prevalence across four lipid parameters. TC=total cholesterol; LDL-C= low density lipoprotein cholesterol; HDL-C= high-density lipoprotein cholesterol; TG=triglycerides. Data derived from National Health Laboratory Service (NHLS) records, 2020-2-24. Overall dyslipidaemia prevalence: 80.8% (any abnormal parameter).

#### 4. Discussion

The study revealed a high prevalence of lipid profile alterations among HIV patients on HAART in rural Eastern Cape primary Healthcare facilities, with 53.8% exhibiting hypercholesterolemia (TC

abnormal), 61.4% elevated LDL-C, 38.6% low HDL-C, and 60.5% hypertriglyceridemia [15]. Overall dyslipidaemia affected over 80% of participants when considering any abnormality, aligning with the dual metabolic burden expected in long-term HAART recipient [16].

#### 4.1. Comparison with Existing Literature

These findings corroborate regional and global patterns. A 2023 South African meta-analysis reported hypercholesterolemia (50-60%) and hypertriglyceridemia (55-65%) rates comparable to this study, particularly among NNRTI AND PI-based prevalent in public sector rollout [17]. The Soweto HIV cohort similarly documented 54% dyslipidaemia after 2 years of ART, while Western Cape studies noted 62% hypertriglyceridemia mirroring the 60.5% TG elevated here. Higher LDL-C prevalence (61.4%) than some African cohorts (40-50%) may reflect longer HAART exposure or dietary factors in rural OR Tambo, where access to lipid-friendly foods is limited [18].

Low HDL-C at 38.6% appears lower than expected (typically 40-50%), possibly due to Low HDL-C at 38.6% appears lower than expected (typically 40-50%), possibly due to gender distribution (72.4%, n=268; 27.6% male, n=102 (Figure 3.3), as females typically exhibit higher baseline HDL-C levels, or dolutegravir-based regimens showing HDL sparing effects in recent trials. Gender distribution (females often have higher baseline HDL) or dolutegravir-based regimens showing HDL-sparing effects in recent trials. Rural PHC settings amplify these risks: suboptimal monitoring (only 10-20% receive annual lipids per guidelines) and comorbidities like TB exacerbate dyslipidaemia via inflammation [19].

#### 4.2. Clinical and Public Health Implications

In Eastern Cape, where CVD mortality rivals HIV, these silent epidemic demands NCD-HIV integration. Rural facilities face unique barriers in frequent phlebotomy, nurse shortages, competing TB/HIV priorities yet handle 80% of ART delivery [20]. High prevalence underscores urgency for point-of-care lipid testing and first-line regimen shifts to INSTIs like dolutegravir/lamivudine/tenofovir, which show 20-30% lower dyslipidaemia rates [21].

#### 4.3. Strengths

This study provides robust, facility-level data on HAART-associated dyslipidaemia in rural Eastern Cape primary healthcare, a setting underrepresented in literature dominated by urban/tertiary cohorts. The census approach (n=370) exceeded calculated sample size, enhancing precision and generalizability within OR Tambo District. Retrospective use of NHLS-accredited lab data ensured high-quality, standardized lipid measurements with establishing quality controls.

#### 4.4. Limitations

Reliance on secondary data precluded adjustment for unrecorded confounders like diet, smoking, exercise, or family history, potentially influencing lipid profiles. Cross-sectional design limits causality inference between HAART regimens/ duration and dyslipidaemia longitudinal effects remain unclear. Missing data risk exists despite complete inclusion of eligible records, and generalizability beyond rural Eastern Cape PHHCs may be limited due to regional socioeconomic/demographic factors.

## 5. Conclusions

Lipid alterations affect over 80% of rural HAART patients in Eastern Cape PHHCs, with hypertriglyceridemia (60.5%) and elevated LDL-C (61.4%) predominant. Routine screening regimen optimization, and lifestyle interventions are essential to mitigate CVD risk in this high-burden settings. Findings support policy for metabolic monitoring in national HIV programs, aligning with South Africa's 2024-2029 strategic Plan. Future prospective studies should explore longitudinal trends and intervention efficacy.

**Author Contributions:** Conceptualization, E.B.K and T.A.; methodology, E.B.K.; formal analysis, M.M and O.L.A.; investigation, E.B.K.; resources, T.A.; data curation, L.M.F.; writing—original draft preparation, E.B.K. and O.L.A.; writing—review and editing, T.A.; visualization, E.B.K. and O.L.A.; supervision, T.A.; project administration, E.B.K.; funding acquisition, T.A. All authors have read and agreed to the published version of the manuscript.

**Funding:** This research received no specific grant from any funding agency in public, commercial, or non-profit sectors.

**Institutional Review Board Statement:** The study was conducted following the Declaration of Helsinki and approved by the Research Ethics and Biosafety Committee of the Faculty of Medicine and Health Sciences of Walter Sisulu University (ref. no. HREC 461/2025) and Eastern Cape Department of Health (ref. No. EC\_202601\_019).

**Informed Consent Statement:** Informed consent was obtained from all subjects involved in the study.

**Data Availability Statement:** Data can be requested from the corresponding author.

**Acknowledgments:** I sincerely thank you supervisor, Professor T. Apalata and Dr Oluwakemi Laguda-Akingba, for their invaluable guidance and support throughout my research. I also appreciate Professor EV Blanco-Blanco for his mentorship and insightful contributions. Special thanks to Dr Pulido for expert advice and constructive feedback. Lastly, I acknowledge the support and resources provided by Walter Sisulu University, which facilitated this work.

**Conflicts of Interest:** The authors declare no conflicts of interest.

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