ORIGINAL ARTICLE

JIACM 2026; 27 (2): 111-115

Metabolic Profile in ART-Naïve HIV Patients After Initiation of Antiretroviral Therapy: A Prospective Study

Jitendra Kumar Doneria, Nirmal Kumari**, Priyanka Gautam***, Deepak Kumar Daunaria****, Pinky Verma*****, Saurabh Tripathi**, Krishna Gopal Vishwakarma*******

Abstract

***Background:** As people with HIV have an increased survival rate, the focus has moved to metabolic changes in the long-term as a result of antiretroviral therapy. Over time, these changes are becoming important in terms of morbidity. The assessment of early metabolic changes after therapy initiation is thus necessary to optimise long-term care of patients.*

***Methods:** This prospective cohort study involved 57 persons who had a recent HIV diagnosis, who had never been treated, and were referred to a tertiary care centre. Everyone was started with a typical first-line treatment including tenofovir, lamivudine, and dolutegravir. Laboratory tests and physical measurements, such as lipid parameters, hepatic indicators, renal indices, and glycated haemoglobin were measured during initial evaluation, six months, and twelve months.*

***Results:** Average body weight, body mass index, and waist circumference had significant increases over a period of twelve months ($p < 0.0001$). Follow-up also revealed a significant increase in the circulating triglyceride concentrations ($p < 0.0001$). Conversely, other biochemical measures, such as high-density lipoprotein, low-density lipoprotein, total cholesterol, hepatic, renal, and glycated haemoglobin, did not show significant difference.*

***Conclusion:** The introduction of antiretroviral therapy in ART-naive patients with HIV was linked to substantial improvements in anthropometric parameters and triglycerides over a period of one year of treatment. The rest of the biochemical parameters were stable, which suggests good short-time metabolic tolerance. It is advisable to monitor body composition and lipid parameters on a regular basis to determine early metabolic alterations and minimise long-term cardiometabolic risk.*

***Key words:** HIV; antiretroviral therapy; metabolic profile; triglycerides; body mass index.*

Introduction

Human immunodeficiency virus (HIV) infection is a significant global health concern despite the development of diagnostics and treatment, and has resulted in high morbidity and mortality rates, especially in low- and middle-income nations. Combination antiretroviral therapy (ART) has turned HIV into a chronic and controllable disease by suppressing viral replication, enhancing the immune system, and decreasing opportunistic infections, thus greatly increasing survival and quality-of-life[1]. As people with HIV have longer lifespans, new co-morbidities including metabolic abnormalities such as weight gain, dyslipidaemia, disturbed glucose metabolism, insulin resistance, and abnormal fat distribution have become increasingly important causes of morbidity[2]. Despite the fact that modern ART regimens, especially the ones with integrase strand transfer inhibitors (tenofovir, lamivudine, and dolutegravir) are more tolerable than former therapies, they also can affect metabolic pathways and lead to alterations in body weight, composition, and lipid profile[3]. These metabolic changes are multifactorial and include chronic immune stimulation, chronic inflammation, immune reconstitution during ART initiation (so-called return to health phenomenon), direct drug action on adipocyte and insulin signaling pathways and host factors such as age, sex, nutritional status, lifestyle, and genetic predisposition[4,5]. Assessment of metabolic parameters in ART-naïve HIV patients is necessary to differentiate disease-related alterations and therapy-induced effects and allow early detection of patients with risk of developing long-term cardiometabolic complications. Especially in resource-limited countries such as India where late presentations and increasing cardiovascular risk factors co-exist. Anthropometric data like body weight, body mass index, waist circumference, and biochemical parameters like lipid profile, liver and renal functions test, and glycated haemoglobin among others are useful indicators of metabolic status, with dyslipidaemia, in particular, hypertriglyceridaemia being one of the most frequently reported abnormalities with long-term implications[6]. Nonetheless, there are few studies on early metabolic alterations with the initiation of ART in ART-naïve patients in tertiary care units because most studies

**Associate Professor, **Senior Resident, ***Assistant Professor, ******Junior Resident, Department of Medicine, ****Assistant Professor, Department of Critical Care Medicine, Sarojini Naidu Medical College, Agra - 282 002, Uttar Pradesh; *****Assistant Professor, Department of Ophthalmics, People's College of Medical Sciences and Research Centre, Bhopal - 462 037, Madhya Pradesh. Corresponding Author: Dr Nirmal Kumari, Junior Resident, Department of Medicine, Sarojini Naidu Medical College, Agra - 282 002, Uttar Pradesh. Tel: 7080061590, E-mail: nirmalkumari231111@gmail.com*

concentrate on long-term therapy. Thus, the current study was carried out to prospectively assess the anthropometric and metabolic variables after antiretroviral therapy in ART-naïve HIV patients to define the initial metabolic changes.

Aim and Objectives

The aim of this study was to examine alterations in physical measurements and metabolic indicators following initiation of antiretroviral therapy in previously untreated individuals with HIV infection. The study focused on tracking variations in body weight, body mass index, and waist circumference at baseline, six months, and twelve months after the start of treatment.

Additionally, the study evaluated changes in lipid-related parameters and assessed variations in hepatic markers, renal indicators, and glycated haemoglobin over a one-year observation period to better understand the metabolic effects associated with antiretroviral therapy.

Material and Methods

A prospective cohort study was conducted in the Antiretroviral Therapy unit over twelve months (May 2022 to April 2023), in a teaching institution after obtaining clearance of the Institutional Ethics Committee. Written consent was taken from all participants before enrolment. A total of 57 people who were recently confirmed to have HIV infection, previously untreated with antiretroviral medication, were recruited.

People who had co-morbidities that are known to affect metabolic outcomes, such as diabetes mellitus, tuberculosis, malignancy, nephrotic syndrome, chronic hepatic disease, thyroid abnormalities or anemia were excluded. All participants were initiated on routine first-line therapeutic plan of tenofovir, lamivudine, and dolutegravir as per NACO guidelines, and were followed up over a one year period with evaluation at baseline, 6 months, and 12 months.

Physical measurements were done, such as weight of the body, body mass index, and waist circumference documented at every visit by standardised recordings. Lab-assessment incorporated lipid-related measures (total cholesterol, triglycerides, HDL, LDL and VLDL), hepatic indicators, renal indicators, and glycated haemoglobin.

The main endpoints were variation in physical and biochemical indicators with time. All data were digitized and analysed with statistical software. Numerical data were calculated based on measures of central tendency and dispersion and categorical variables were presented in number and percentage. The evaluation of temporal changes was performed with the help of relevant comparative methods, such as variance-based methods. A pre-set limit was used on determine statistical relevance.

Results

A total of 57 ART-naïve HIV-positive patients were enrolled and followed for twelve months after initiation of antiretroviral therapy. Among them, 36 (63.16%) were male and 21 (36.84%) were female. The majority of patients belonged to the 21 - 30 years age group, followed by 31 - 40 years, indicating a higher prevalence among young adults.

Changes in Anthropometric Parameters

A progressive increase in body weight, body mass index (BMI), and waist circumference was observed over the 12-month follow-up period. These changes were statistically significant overall ($p < 0.0001$). Post-hoc analysis showed that the significant differences were primarily observed between baseline and twelve months, while changes between intermediate time points were not statistically significant.

The increase in waist circumference indicates a rise in central adiposity over time. Detailed values and statistical comparisons are presented in Table I and illustrated in Figs. 1 - 3.

Table I: Change in mean anthropometric parameters from baseline to 12 months after ART initiation.

Parameter	0 Months (Mean ± SD)	6 Months (Mean ± SD)	12 Months (Mean ± SD)	F-Ratio	p-value
Weight (kg)	52.8 ± 10.4	57.1 ± 11.2	61.3 ± 11.0	1024.8	**<0.0001**
BMI (kg/m^2)	22.1 ± 3.4	24.0 ± 3.5	25.7 ± 3.4	824.3	**<0.0001**
SGOT (U/L)	40.9 ± 20.4	45.6 ± 24.4	41.1 ± 19.0	1.16084	0.316962
SGPT (U/L)	42.2 ± 24.6	41.4 ± 25.1	36.3 ± 17.1	1.5332	0.220339
Urea (mg/dL)	27.3 ± 12.8	26.0 ± 8.5	26.5 ± 6.9	0.30786	0.735641
Creatinine (mg/dL)	0.9 ± 0.2	1.0 ± 0.29	1.6 ± 0.4	1.11767	0.330662

HDL (mg/dL)	53.4 ± 10.9	53.1 ± 10.2	50.2 ± 9.4	38.9	**<0.0001**
Triglycerides (mg/dL)	112.8 ± 34.2	113.4 ± 33.0	129.7 ± 35.0	51.71911	**<0.0001**
VLDL (mg/dL)	25.6 ± 8.2	25.3 ± 8.4	25.3 ± 8.9	3.09364	0.049232
LDL (mg/dL)	103.3 ± 39.0	102.8 ± 38.7	108.9 ± 37.8	43.4314	**<0.0001**
Total Cholesterol (mg/dL)	154.2 ± 56.8	152.2 ± 56.4	151.3 ± 57.6	2.36939	0.098211
HbA1c (%)	5.4 ± 0.2	5.5 ± 0.2	5.5 ± 0.2	1.06064	0.349685
Waist Circumference (cm)	81.2 ± 10.64	85.1 ± 10.80	91.4 ± 11.1	3318.721	**<0.0001**

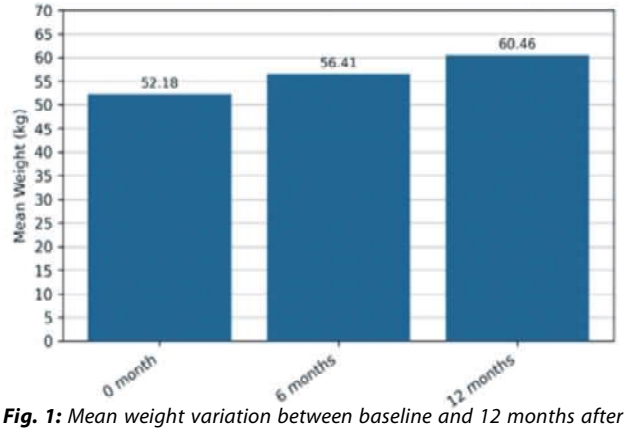

Fig. 1: *Mean weight variation between baseline and 12 months after ART initiation.*

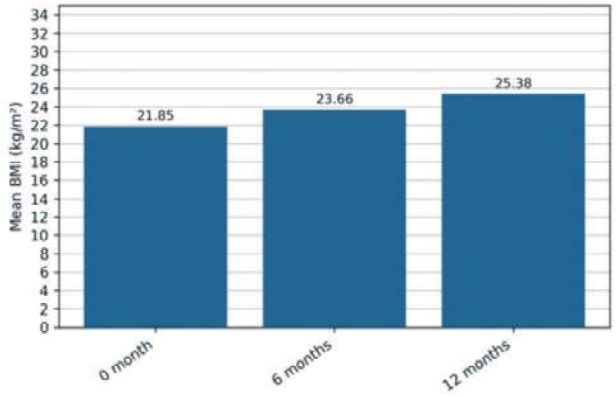

Fig. 2: *Mean BMI variation between baseline and 12 months after ART initiation.*

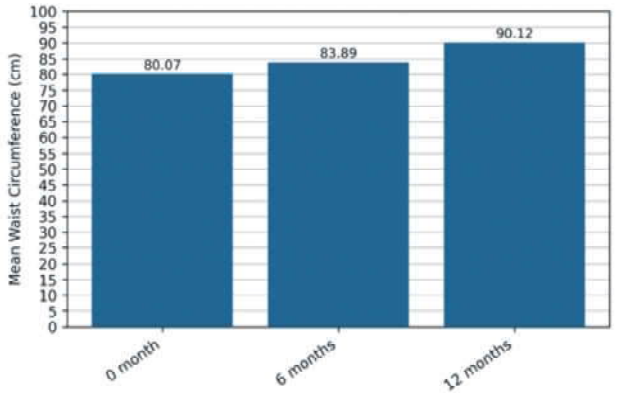

Fig. 3: *Mean waist circumference variation between baseline and 12 months after ART initiation.*

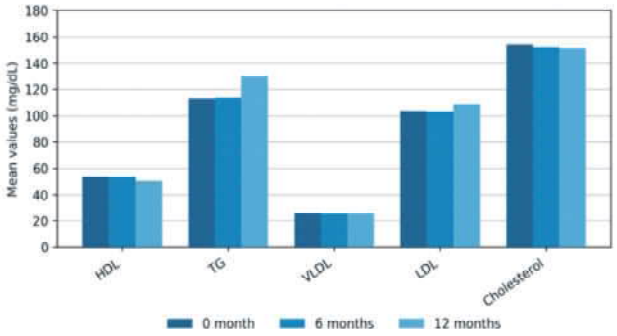

Fig. 4: *Variation in mean lipid profile parameters between baseline and 12 months after ART initiation.*

Changes in Biochemical Parameters

Triglyceride levels showed a progressive and statistically significant increase over the follow-up period ($p < 0.0001$), with significant differences observed between baseline and twelve months, as well as between six and twelve months. In contrast, other lipid parameters, including HDL, LDL, VLDL, and total cholesterol, showed minimal changes over time and did not demonstrate consistent clinically significant variation.

Liver function parameters (SGOT and SGPT) and renal function parameters (urea and creatinine) remained stable throughout the study period, with no statistically significant changes observed. Glycated haemoglobin (HbA1c) showed a slight increase; however, this change was not statistically significant.

The overall variation in lipid profile parameters over the follow-up period is depicted in Fig. 4.

Discussion

The current study assessed the metabolic profile of ART naïve HIV patients who visit an ART tertiary care hospital and measured the anthropometric and biochemical changes.

Increased body weight may reflect a combination of the "return-to-health" phenomenon following viral suppression, improved appetite, and reduced catabolic effects of chronic HIV infection. Comparable findings have been reported in previous studies, where weight gain after initiation of ART was attributed to immune restoration and improved nutritional status[5].

The considerable increase in BMI after 12 months also indicates the existence of ART-related alterations in overall body mass. Even though the initial gains in BMI can be helpful in malnourished patients, higher and persistent gains can expose patients to overweight and obesity. This is of clinical importance, because high BMI is known to be one of the risks of cardiovascular disease and metabolic syndrome. Past research has revealed inconsistent impacts of ART on BMI that point to the impact of the population, baseline nutrition and course of treatment[6].

A statistically significant increase in waist circumference was found at follow-up exhibiting a rise in central adiposity. Of specific interest is the central fat accumulation, which is highly linked to insulin resistance and cardiovascular risk. Various studies have reported ART-related changes in fat distribution, central obesity, that have been attributed to the intricate interplay between antiretroviral drugs, adipocyte functions, and inflammatory processes[7]. The outcome is an apparent rise in waist circumference of this group, which highlights the importance of regular surveillance of central obesity in ART-using HIV patients.

Of all biochemical parameters, the levels of triglyceride showed a statistically significant rise throughout the 12-month follow-up time. Among the most common metabolic abnormalities in HIV patients taking ART, dyslipidaemia, especially hypertriglyceridaemia, is one of them. This increase in triglyceride levels was reported by Daniyam and Iroezindu and Yinzhong *et al*, who also reported an increase in triglyceride levels in HIV-infected people after they started taking ARTs[8,9]. High triglycerides are a risk factor in cardiovascular difease and should be monitored and treated early.

Other lipid parameters such as HDL, LDL, VLDL, and total cholesterol, did not exhibit statistically significant alterations throughout the study period. There are previous studies which have reported similar mixed outcomes with some showing LDL and total cholesterol increase and others showing slight or no change[10,11]. The relatively steady lipid profile excluding triglycerides in the current study could be an indication of the relatively good metabolic tolerance of the TLD-based regimen.

Liver parameters such as SGOT and SGPT were consistent during the study and no considerable highs were recorded. This indicates that ART regimen was tolerated well in terms of hepatic functioning in the initial year of therapy. The results seem to be consistent with other researchers who found very low clinically-significant hepatotoxicity with current ART regimens[12]. On the same note, parameters of renal function, such as serum urea and creatinine did not experience significant changes in the course of the follow-up, and therefore renal function was preserved throughout the study.

HbA1c as a measure of glycaemic status demonstrated a marginal increase over time, but this was not significant. This implies that exposure to ART over short-term did not have a significant effect on glucose metabolism in this group. Little changes in HbA1c levels among HIV patients on ART have also been reported in the previous literature, and the glucose dysregulation might appear in the long-term or with other risk factors[12-14].

On the whole, the results of this research point out that, although the introduction of ART among ART-naïve HIV-positive patients results in considerable changes in anthropometric parameters and triglycerides, the majority of other biochemical parameters do not change significantly in the initial year of treatment. The findings underscore the need to monitor early metabolism, especially weight, waist circumference and triglyceride levels to detect patients who are prone to long-term cardiometabolic complications. The research has some limitations such as a rather small sample size and the period of follow-up. More multicentric studies with longer follow-up should be conducted to have a better understanding of the long-term metabolic impact of ART and clinical implications. However, the current study contributes to understanding the early metabolic alterations upon the ART initiation in a tertiary care environment and supports the necessity of the metabolic monitoring as an inseparable part of the HIV treatment.

Conclusion

This paper proves that the implementation of antiretroviral treatment in ART-naïve HIV patients who receive medical care at a tertiary care ART center is linked to the presence of meaningful alterations in the chosen metabolic parameters within a 12-month follow-up. Significant changes of body weight, body mass index, waist circumference, and serum triglyceride were recorded, which showed a change in body composition and lipid metabolism after the initiation of ART. These results indicate the predisposition to central adiposity and dyslipidaemia, which can predispose the individuals with HIV to cardiovascular disease in the long run. Conversely, other biochemical parameters, such as liver function tests, renal function tests, HbA1c, and the majority of the lipid profile, did not change much within the study period. It indicates that the ART regime implemented was generally well-tolerated in the short-term with regards to hepatic, renal,

and glycaemic outcomes. The results underline the importance of periodic monitoring of anthropometric variables and lipid profiles, especially triglyceride levels, in HIV patients starting ART to allow early lifestyle modifications and prevention programs to reduce possible cardiometabolic dangers in the future. The metabolic long-term consequences of ART and how to make a comprehensive care plan on individuals with HIV are issues that should be studied thoroughly in bigger samples and longer follow-up.

Limitations

There are some limitations in this research that one ought to bear in mind when explaining the results. One, the sample size was small and it was chosen at a single tertiary care ART center, which can limit the generalisation of results to other settings or populations. Second, they were limited to 12 months of follow-up which is not sufficient to identify the long-term metabolic effects of antiretroviral therapy, especially in terms of cardiovascular and diabetic outcomes. Third, the authors did not have a control group of HIV-negative persons or patients who were not on ART, which limits the possibility to differentiate between the changes that could be explained only by ART and the ones that could be explained by HIV infection or immune reconstitution. Fourth, lifestyle habits like diet, physical activities, smoking, and alcohol intake were not measured in a quantitative manner and these might have contributed to the metabolic outcomes. Also, the factors of insulin resistance and biomarkers of inflammation were not measured, which could have given more understanding of the mechanisms of observed metabolic shifts. Imaging techniques were also not carried out to analyze body composition, which restricts accurate determination of fat redistribution. Nevertheless, the study yields useful prospective information on initial metabolic alterations of ART initiation in ART-naïve HIV patients despite the aforementioned limitations.

References

1. Van Heuvel Y, Schatz S, Rosengarten JF. Infectious RNA: Human immunodeficiency virus (HIV) biology, therapeutic intervention, and the quest for a vaccine. *Toxins* 2022; 14 (2): 138.
2. World Health Organisation. Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022 - 2030. World Health Organisation; 2022 Jul 18.
3. Thompson MA, Aberg JA, Hoy JF. Antiretroviral treatment of adult HIV infection: 2012 recommendations of the International Antiviral Society – USA panel. *JAMA* 2012; 308 (4): 387-402.
4. Doshi TM, Mistry RA, Mehta MN. Clinical profile of HIV positive patients attending ART centre of a tertiary care hospital.
5. Alebel A, Demant D, Petrucka PM. Weight change after antiretroviral therapy initiation among adults living with HIV in Northwest Ethiopia: a longitudinal data analysis. *BMJ Open* 2022; 12 (2): e055266.
6. Schouten JA, Berrevoets MA, Hulscher ME. Quality indicators to measure appropriate antibiotic use: some thoughts on the black box. *Clini Infe Dis* 2017; 64 (9): 1295.
7. Ferraro B, Morrow MP, Hutnick NA. Clinical applications of DNA vaccines: current progress. *Clini Infec Dis* 2011; 53 (3): 296-302.
8. Daniyam CA, Iroezindu MO. Lipid profile of anti retroviral treatment naive HIV-infected patients in Jos, Nigeria. *Annals of Medical and Health Sciences Research* 2013; 3 (1): 26-30.
9. Shen YinZhong SY, Wang JiangRong WJ, Wang ZhenYan WZ. Prevalence of dyslipidaemia among antiretroviral-naïve HIV-infected individuals in China.
10. Kohli R, Shevitz A, Gorbach S. A randomised placebo controlled trial of metformin for the treatment of HIV lipodystrophy. *HIV Med* 2007; 8 (7): 420-6.
11. Adewole OO, Eze S, Betiku YE. Lipid profile in HIV/AIDS patients in Nigeria. *African Health Sci* 2010; 10 (2): 144.
12. da Cunha J, Maselli LM, Stern AC. Impact of antiretroviral therapy on lipid metabolism of human immunodeficiency virus-infected patients: old and new drugs. *World J Virolo* 2015; 4 (2): 56.
13. Francisco C, Gonzales E, Yu MG. Metabolic profile of people living with HIV in a treatment hub in manila, philippines: a pre- and post-antiretroviral analysis. *J ASEAN Federati Endocri Soc* 2022; 37 (1): 53.
14. Joshi KS, Saraf UU, Gujarathi RY. Analysis of the metabolic syndrome and its association with cART in HIV positive individuals receiving various cART regimens with review of literature. *medRxiv* 2022; 2022-03.