



To Assess the Impact of Antiretroviral Therapy on Renal Function in Hiv-Infected Patients

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(Received: 16 May 2025

Revised: 20 June 2025

Accepted: 12 July 2025)

KEYWORDS

HIV, TLD,
Renal
impairment,
eGFR

ABSTRACT:

Although antiretroviral therapy (ART) has revolutionized the treatment of HIV infection, it can be harmful to renal function, especially when used with some nephrotoxic drugs. HIV-infected patients frequently have chronic kidney disease (CKD), which makes continuous renal health monitoring necessary. With emphasis on the effects of frequently administered antiretroviral medications, this study attempts to evaluate the effect of ART on renal function in people with HIV.

Material & Methods: Prospective cohort study was conducted at Shri Mahant Indires Hospital's Outpatient Department in Uttarakhand with 40 HIV-infected patients receiving ART. Patients aged 18 and older who agreed to participate were eligible, while those with contraindications to ART were excluded. Renal function parameters such as serum creatinine, estimated glomerular filtration rate (eGFR), proteinuria, and serum urea were measured monthly. To analyze changes in renal biomarkers, statistical analyses were performed using R Studio, applying the Wilcoxon signed-rank test and the paired t-test.

Results: The study identified significant changes in renal biomarkers after ART initiation. The number of patients with elevated serum creatinine levels (≥ 1.6 mg/dL) increased from one to five. The eGFR levels showed a concerning trend, with more patients falling into lower eGFR categories after treatment. Proteinuria levels rose from 19 patients (< 150 mg/day) to 26 patients (number_1 mg/day). Serum urea levels also increased notably, suggesting possible renal impairment caused by ART.

Conclusion: The findings highlight the nephrotoxic potential of certain antiretroviral drugs, especially Tenofovir disoproxil fumarate, emphasizing the importance of regular renal function monitoring in HIV-infected patients on ART. Early detection of renal impairment is essential for prompt intervention, and healthcare providers should explore alternative ART options for patients showing signs of renal failure. Further research is needed to develop effective strategies to reduce renal toxicity and improve long-term kidney health in this population.



INTRODUCTION

HIV medications have a considerable impact on renal function, with some antiretroviral regimens being nephrotoxic. Chronic kidney disease (CKD) can occur as a result of both drugs and the underlying HIV infection, so individuals undergoing therapy must be closely monitored for kidney health. The use of antiretroviral medication (ART) in HIV treatment has revolutionized disease management, but it also entails hazards for renal function. Certain antiviral medicines are linked to nephrotoxicity, which can result in acute kidney injury or chronic kidney disease (CKD). This demands a thorough grasp of how these drugs influence kidney function.

Renal impairment has been associated with several antiretroviral medications, most notably tenofovir disoproxil fumarate (TDF). In rare instances, TDF can result in Fanconi syndrome, which is characterized by renal glycosuria, proteinuria, and hypophosphatemia, as well as proximal tubular dysfunction. Long-term use raises the chance of acquiring these disorders, particularly in people who already have renal problems.^[1] HIV patients frequently experience polypharmacy, especially elderly people who may be taking several drugs for related illnesses. This raises the possibility of medication interactions that could make renal impairment worse. To stop more problems, it becomes essential to monitor renal function in these patients. For individuals receiving nephrotoxic ART, routine renal function screening is crucial. This involves determining the glomerular filtration rate (eGFR) and evaluating serum creatinine levels. When using medications like cobicistat and dolutegravir that block tubular creatinine excretion, high creatinine levels may not always be a sign of actual renal impairment. Tenofovir alafenamide (TAF), a newer formulation, has a superior renal safety profile than TDF.^[2] TAF is metabolized differently, resulting in lower amounts in the proximal renal tubules, potentially reducing the risk of nephrotoxicity. Ongoing research is looking at the long-term safety of TAF in HIV treatment. Renal impairment in HIV patients can cause consequences such as electrolyte imbalances, increased cardiovascular risk, and the requirement for dose modifications in ART. Clinicians must be cautious while handling these individuals to reduce the risk of renal failure and guarantee appropriate HIV control. Educating patients on the potential renal adverse effects of their drugs is

critical. Patients should be advised about the necessity of adhering to the prescription ART and attending regular follow-up sessions for renal function monitoring. This proactive strategy can aid in the early detection and treatment of kidney problems. Research on ART's long-term effects on renal function is ongoing. Some patients may develop increasingly chronic kidney disease (CKD), while others may have stable renal function. Customizing treatment strategies requires an understanding of the individual risk variables, such as age, baseline renal function, and comorbidities.^[3]

Epidemiology of renal function in the Setting of HIV Infection with ART therapy:

One major issue for people living with HIV, especially those receiving antiretroviral medication (ART), is renal function deterioration. Research shows that this population has a very high prevalence of renal impairment, with low CD4 counts, diabetes, and hypertension all raising the risk. Depending on the particular regimens employed and the patients' preexisting health status, starting ART has been linked to both improvements and declines in renal function. The prevalence of renal impairment in people with HIV reveals a complicated interaction between the virus, antiretroviral therapy, and underlying comorbidities.^[4] Although ART can slow the progression of HIV-related kidney disease, research indicates that it may potentially have nephrotoxic side effects, especially when used with specific medication classes. To control and reduce the hazards related to HIV and its treatment, it is crucial to continuously evaluate renal function in this population. For those with HIV, especially those receiving antiretroviral medication (ART), renal function deterioration is a serious concern. Studies show that elements like diabetes, hypertension, and low CD4 counts increase the likelihood of developing chronic kidney disease (CKD), and the prevalence of renal dysfunction in this population is particularly high. ART beginning has been linked to both improvements and declines in renal function, contingent on the particular regimens employed and the patients' preexisting health state. A sophisticated understanding of the intricate interactions between the viruses, ART, and pre-existing comorbidities is also required, as the epidemiology of renal impairment in HIV-infected persons reveals. According to research, antiretroviral therapy (ART) can slow the progression of HIV related kidney disease, but



it can also have nephrotoxic side effects, especially when combined with specific medication classes. To control and reduce the risks related to HIV and its treatment, renal function must be continuously monitored in this population. There is optimism for better renal health outcomes for HIV-infected people due to the changing landscape of ART regimens, which includes the release of novel medicines that may have less renal toxicity. To maximise patient care and avoid long-term problems, customised treatment regimens and routine renal evaluations are still essential.^[5]

1. Assessment of Adults and Adolescents with HIV Infection

Individuals diagnosed with HIV at the ICTC should enroll in ART centers for care and treatment services. Adolescents are described as those aged 10 to 19 years. Rapid ART initiation requires a thorough clinical assessment, history, physical examination, and basic laboratory tests.

This section focuses on assessing HIV-infected adults and adolescents. The steps for the initial evaluation of PLHIV are as follows:

Step 1: Clinical assessment and medical history

Step 2: Physical examination

Step 3: Baseline laboratory evaluation

A. Clinical Assessment

Once enrolled in an ART center, PLHIV should undergo a full clinical assessment to determine baseline status and rule out OIs. This assists in determining the clinical stage of HIV infection, identifying current HIV-related illnesses that may require treatment, identifying prior exposure to ARVs, determining the need for OI prophylaxis, and identifying coexisting medical conditions such as Diabetes, Hypertension, Hepatitis, or other treatments that may influence the choice of ARV drugs.^[6]

B. Medical history assessments

HIV testing should be accompanied by thorough screening for tuberculosis (TB) symptoms. For adults,

key symptoms to assess include fever, cough, weight loss, and night sweats. In children, the focus should be on fever, cough, poor weight gain or reported weight loss, and any history of contact with a TB case. Additionally, it is important to consider other symptoms such as headaches, impaired focus, and seizures. A comprehensive medical history is essential, including any history of diabetes, hypertension, and other comorbidities, as well as a family history of tuberculosis. Prior exposure to antiretroviral therapy (ARVs) and a history of sexually transmitted infections (STIs) should also be documented. Furthermore, it is crucial to evaluate HIV risk behaviors, such as having multiple partners, belonging to key populations, or engaging in injecting drug use, along with any substance abuse issues related to alcohol, tobacco, or drugs. Other factors to consider include pregnancy and contraception, allergies, current medications and vaccines, nutritional status, and a psychosocial assessment to ensure a holistic approach to patient care.^[7]

C. Symptoms of Serious Disease

If a person living with HIV exhibits any of the following indicators of serious illness, they should be referred for specialist evaluation immediately:

- Temperature of 39°C (102.2°F) or higher accompanied by a headache
- Respiratory rate of 30 breaths per minute or more
- Heart rate exceeding 120 beats per minute
- Pulse oximeter reading below 90%

Additionally, symptoms indicating a medical emergency include altered mental status (such as confusion, unusual behavior, or reduced consciousness), neurological issues (including persistent severe headache, seizures, paralysis, difficulty speaking, or rapid deterioration of vision), inability to walk unaided, and any other condition that requires urgent medical management. Prompt referral and evaluation are critical in these situations to ensure appropriate care and intervention.^[6, 7]

Nutritional Assessment

Good nutrition is essential for maintaining health and quality of life for everyone, while poor nutrition can hinder a person's ability to work and remain active. For



people living with HIV (PLHIV), inadequate nutrition exacerbates the effects of the virus by further compromising the immune system. This can lead to frequent illnesses and hinder the body's ability to repair and replace cells and tissues, resulting in significant weight loss and potentially accelerating disease progression. Dietary intake plays a crucial role in adherence to antiretroviral therapy (ART) and its effectiveness. HIV and related infections increase the body's requirements for energy, protein, and micronutrients such as iron, zinc, and vitamin C. Opportunistic infections (OIs) like tuberculosis, pneumonia, and diarrhea further elevate these nutritional demands, contributing to a decline in nutritional status and creating a vicious cycle between HIV infection and malnutrition. Providing appropriate nutritional support from the early stages of HIV infection can help prevent malnutrition and associated deficiencies, as well as support immune system function. Nutritional care and support—including counseling, education, information sharing, and connections to social welfare programs—are vital components of a comprehensive care package for all PLHIV, including adults, adolescents, and children living with HIV (CLHIV). A body mass index (BMI) of less than 18.5 kg/m² is recognized as an independent risk factor for morbidity and mortality among HIV-positive adolescents and adults. Therefore, an initial assessment of nutritional status, along with targeted follow-up care, is crucial in the comprehensive management of HIV-positive patients. Focusing on nutritional care can enhance adherence to ART, improve retention in care, and support individuals in leading productive lives.^[8]

2. ART in Adults and Adolescents

Over the past two decades, there has been a significant decline in HIV-related mortality and morbidity, largely due to the increased availability of affordable, more effective, and less toxic antiretroviral (ARV) medications. Antiretroviral therapy (ART) involves the use of a combination of at least three ARV drugs from different classes to inhibit the replication of HIV and reduce viral load to undetectable levels. Sustained suppression of viral replication allows for the restoration of immune function, which is indicated by an increase in CD4 cell counts. An increase in CD4 count contributes to a slowdown in disease progression, a reduced frequency of opportunistic infections (OIs), improved

quality of life, and increased longevity. The advancements achieved through ART have shifted the perception of HIV infection from being viewed as a "virtual death sentence" to a "chronic manageable illness." Previously referred to as Highly Active Antiretroviral Therapy (HAART) and Combination Antiretroviral Therapy (cART), ART has become a cornerstone of HIV treatment and management.^[9]

A. Goals of Antiretroviral Therapy

While antiretroviral therapy (ART) cannot cure HIV infection, as current ARV drugs are unable to eradicate the virus from the human body, it plays a crucial role in managing the disease. During the early stages of acute HIV infection, a pool of latently infected CD4 cells is established, allowing HIV to persist in various organs, cells, and fluids (such as the brain, liver, and lymphoid tissue) even when plasma viral load is suppressed to undetectable levels by ART.

The primary goals of ART include achieving maximal and sustained reduction of plasma viral load and restoring immunological functions. A decrease in viral load not only improves individual health but also reduces the transmissibility of the virus, thereby decreasing the incidence of new HIV infections. The specific goals of ART are outlined in the following Table 1.

Table 1: Goals of ART

Goals of ART	Description
Clinical Goals	Increase survival and improve quality of life
Virological Goals	Achieve the greatest possible sustained reduction in viral load
Immunological Goals	Promote immune reconstitution, both quantitatively and qualitatively
Therapeutic Goals	Sequence drugs rationally to meet clinical, virological, and immunological goals while preserving future treatment options, minimizing drug toxicity, and facilitating adherence
Preventive Goals	Reduce HIV transmission through effective suppression of viral load



With continued viral suppression, the destruction of CD4 lymphocyte cells is minimized, leading to an increase in CD4 counts over time. This increase is associated with a partial restoration of pathogen-specific immune function, resulting in a decreased incidence of opportunistic infections (OIs) and a reduction in morbidity and mortality.

B. Clinical Pharmacology of Commonly Used ARV Drugs

I) Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)

The first effective class of antiretroviral (ARV) drugs discovered was the nucleoside analogues, which function by incorporating themselves into the viral DNA, thereby halting the replication process. This results in incomplete DNA that cannot produce new viruses. Nucleotide analogues operate similarly to nucleosides but possess a nonpeptidic chemical structure. The details of commonly used ARV drugs in this class are summarized in Table 2.

Table 2: Commonly Used NRTIs

Generic Name	Dose	Adverse Effects
Tenofovir Disoproxil Fumarate (TDF)	300 mg once daily	Renal toxicity, bone demineralization
Zidovudine (AZT)	300 mg twice daily	Anemia, neutropenia, bone marrow suppression, gastrointestinal intolerance, headache, insomnia, myopathy, lactic acidosis, skin and nail hyperpigmentation
Lamivudine (3TC)	150 mg twice daily or 300 mg once daily	Minimal toxicity, rash (very rare)
Abacavir (ABC)	300 mg twice daily or 600 mg	Hypersensitivity reaction

	once daily	
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II) Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs)

Non-nucleoside reverse transcriptase inhibitors (NNRTIs) inhibit HIV production by binding to the reverse transcriptase enzyme, preventing the conversion of viral RNA to DNA. These drugs are termed "non-nucleoside" inhibitors because, although they act at the same stage as nucleoside analogues, they inhibit the enzyme by directly binding to it rather than acting as chain terminators. The details of commonly used NNRTIs are shown in Table 3.

Table 3: Commonly Used NNRTIs

Generic Name	Dose	Food-Related Advice	Adverse Effects
Efavirenz (EFV)	600 mg once daily (recommended at bedtime to reduce CNS side effects)	Avoid taking after high-fat meals	Central nervous system symptoms (dizziness, somnolence, insomnia, confusion, hallucinations, agitation), personality changes, rash (less common than with NVP)
Nevirapine (NVP)	200 mg once daily for 14 days, then 200 mg twice daily		

Integrase Inhibitors (Integrase Strand-Transfer Inhibitors [INSTIs])

Integrase inhibitors are a class of ARV drugs designed to block the action of integrase, a viral enzyme that



integrates the viral genome into the DNA of the host cell. Since integration is a critical step in retroviral replication, inhibiting this process can halt further viral replication.^[10, 11]

Raltegravir (RAL): Approved for use in 2007, Raltegravir is primarily metabolized by uridine diphosphate glucuronosyltransferase 1A1 and has a single inactive glucuronide metabolite. It does not interact with cytochrome P450 enzymes, exhibiting a low potential for drug-drug interactions. Common adverse effects include nausea, headache, diarrhea, fever, elevated creatine phosphokinase (CPK), muscle weakness, and insomnia. Major toxicities are listed in Table 4.

Dolutegravir (DTG): First approved by the US FDA in 2013 and recommended by WHO in 2019, Dolutegravir is now the preferred drug for treating HIV-positive adults, adolescents, and children (over 6 years old and weighing more than 20 kg) under the National AIDS Control Programme (NACP). DTG is an orally bioavailable INSTI that binds to the active site of integrase, preventing the transfer of viral genetic material into human chromosomes and blocking the strand transfer step essential for HIV replication.^[12]

Dolutegravir is currently recommended for both first-line and second-line treatment regimens.

Table 4: Integrase Inhibitors Used in National Programme

Generic Name	Dose	Adverse Effects
Dolutegravir (DTG)	50 mg once daily	Insomnia (patients with sleep disturbances should be reviewed), headache (persistent cases should be referred), dizziness, tiredness, allergic reactions, weight gain (requires monitoring and patient education)
Raltegravir (RAL)	400 mg twice daily	Rhabdomyolysis, myopathy, myalgia, diarrhea, fever, rash, Stevens-Johnson syndrome, toxic epidermal

		necrosis, hepatitis, hepatic failure, insomnia
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Dolutegravir has several drug interactions, as outlined in Table 5.

Table 5: Drug Interactions with Dolutegravir

Key Drug	Interaction
Amodiaquine	Use an alternative antimalarial agent
Carbamazepine	Use DTG twice daily or substitute with an alternative anticonvulsant
Phenytoin and phenobarbital	Use an alternative anticonvulsant
Dofetilide	Use an alternative antiarrhythmic agent
Metformin	Limit daily dose to 1000 mg and monitor glycemic control
Polyvalent cation products (Al, Ca, Fe, Mg, Zn)	Administer 2 hours before or 6 hours after DTG
Rifampicin	Use DTG 50 mg twice daily or substitute with rifabutin

III) Protease Inhibitors (PIs)

Protease inhibitors function at the final stage of the viral replication cycle, preventing HIV from being successfully assembled and released from infected CD4 cells. All PIs can cause gastrointestinal intolerance, altered taste, abnormal liver function tests, and bone disorders, and they are associated with metabolic abnormalities such as hyperglycemia, insulin resistance, and changes in body fat distribution (lipodystrophy). The details of commonly used PIs are summarized in Table 6.

Table 6: Commonly Used PIs

Generic Name	Dose	Adverse Effects
Atazanavir /ritonavir (ATV/r)	300 mg Atazanavir + 100 mg	Unconjugated hyperbilirubinemia, lipid abnormalities,



	Ritonavir once daily	hyperglycemia, fat maldistribution, nephrolithiasis, cholelithiasis, PR prolongation
Lopinavir/r itonavir (LPV/r)	200 mg Lopinavir/50 mg Ritonavir (fixed-dose tablet) 2 tablets twice daily	Diarrhea, nausea, vomiting, abnormal lipid profiles, glucose intolerance
Darunavir (DRV)	600 mg twice daily (with Ritonavir 100 mg twice daily)	Hepatotoxicity, skin rash (10%), diarrhea, nausea, headache, hyperlipidemia, serum transaminase elevation, hyperglycemia
Ritonavir (RTV)	100 mg once or twice daily (depending on the PI)	Common: GI issues (diarrhea, nausea, vomiting, abdominal pain); Rare: neurological disturbances (including paresthesia)

Co-administration of antitubercular and ARV agents is feasible for most individuals, with Rifampicin-based regimens successfully combined with the NNRTI Efavirenz. However, PIs present significant drug-drug interactions due to their effects on the hepatic cytochrome P450 enzyme system, which can lead to sub-therapeutic plasma concentrations of ARV drugs. For instance, PIs are often contraindicated with potent CYP inducers like Rifampicin. Alternatively, Rifabutin can be used with appropriate dose adjustments. Rifampicin-based regimens may also reduce the bioavailability of Dolutegravir, but it can be used in conjunction with an additional dose of DTG 50 mg every 12 hours during the entire duration of antitubercular therapy.^[13, 14]

C. Monitoring of Patients on ART

Follow-up and monitoring are crucial for patients initiated on antiretroviral therapy (ART) to assess clinical progress, ensure well-being, and identify any adverse drug reactions or toxicities. Monitoring encompasses both clinical and laboratory evaluations, including adherence to ART. Patients should be monitored monthly for clinical progress, side effects of ARVs, and treatment adherence. Clinical and laboratory assessments are conducted at specified intervals for individuals on ART. A combination of clinical and laboratory monitoring should be performed for all people living with HIV (PLHIV) after starting ART, as outlined in Table 7.

Table 7: Monitoring and Follow-Up Schedule for Patients on ART

Monitoring Tool	When to Monitor
Body weight	Every visit
Height/length in children	Every visit
Treatment adherence	Every visit
Clinical monitoring and T-staging	Every visit
4-symptom TB screening	Every visit
Screening for common non-communicable diseases (NCDs) such as hypertension and diabetes mellitus	Every 6 months or as symptoms dictate
Laboratory evaluation based on ART regimen	Every 6 months or as symptoms dictate
CD4 Count	Every 6 months*
Viral load	At 6 months, 12 months, and then every 12 months

*CD4 Count:

1. Routine virological monitoring is available; CD4 testing should be conducted every 6 months and can be discontinued in PLHIV (except those with HIV-2 infection) when the CD4 count exceeds 350 cells/mm³ and the viral load is



below 1000 copies/ml (when both tests are performed simultaneously).

2. CD4 monitoring should be resumed for any patient if:
 - a. The patient has switched due to treatment failure (virologic failure, defined as plasma viral load ≥ 1000 copies/ml).
 - b. The clinician deems it necessary for clinical management at any time.
3. For patients on second/third-line ART, plasma viral load testing should be conducted every 6 months.

Monitoring Indicators:

a) Clinical Monitoring:

- Monthly clinical evaluations.
- Assessment of body weight, overall well-being, and any new symptoms/signs, including 4-symptom TB screening at every visit.
- Monthly evaluation of treatment adherence, including pill counts and self-reported adherence.
- Adherence to ART must be assessed at each visit, with reinforcement through counseling.
- Monitoring for adverse reactions to ART or opportunistic infection (OI) drugs.
- Checking for drug-drug interactions, including all concomitant medications (prescribed and over-the-counter).
- Monitoring for Immune Reconstitution Inflammatory Syndrome (IRIS).

b) Immunological Monitoring:

- CD4 testing should be performed every 6 months.
- Routine virological monitoring is available; CD4 testing can be discontinued in PLHIV (except those with HIV-2 infection) when the

CD4 count exceeds 350 cells/mm³ and plasma viral load is below 1000 copies/ml.

c) Virological Monitoring:

- Conducted at 6 months and 12 months after ART initiation, and then every 12 months.

Interpretation of Plasma Viral Load Testing Results:

PLHIV with a plasma viral load of < 1000 copies/ml should continue the same ART regimen, with subsequent viral load testing as per guidelines.

PLHIV with a plasma viral load of ≥ 1000 copies/ml should receive enhanced adherence counseling for three months, with intensive support from the ART center counselor to improve adherence.

Repeat viral load testing should occur once treatment adherence exceeds 95% for three consecutive months.

If the repeat plasma viral load is < 1000 copies/ml, the patient should continue on the same ART regimen.

If the repeat plasma viral load is ≥ 1000 copies/ml, the patient should be electronically referred to the SACEP (e-SACEP) for further management.

In cases of high viral load, declining CD4 counts, and poor clinical conditions, the ART Medical Officer may refer the patient to SACEP based on a single viral load report for further management.^[15]

d) Laboratory Monitoring:

Laboratory monitoring of PLHIV on ART is vital for identifying ARV-related toxicities, intercurrent illnesses, drug-drug interactions, and other metabolic abnormalities. The frequency and parameters for monitoring depend on the components of the ART regimen. A summary of the recommended laboratory monitoring is presented in Table 8.

**Table 8:** Laboratory Monitoring of Individual ARV Drugs

For all patients on ART, CD4, hemoglobin (Hb), total leukocyte count (TLC), differential leukocyte count (DLC), alanine aminotransferase (ALT), and serum creatinine should be assessed every six months.

Tests for Monitoring Patients on ART (Follow-Up Tests):

Monitoring ARV Drug in Regimen	Monitoring Test	Baseline	15th Day	First Month	Third Month	Sixth Month	Then Every 6 Months	At 12 Months
On Tenofovir-based ART	Serum creatinine	Yes	&	&	Yes	Yes	&	
	Urine for protein	Yes	&	&	Yes	Yes	&	
On Zidovudine-based ART	CBC	Yes	Yes	Yes	Yes	Yes	&	Yes
On Efavirenz-containing ART	Lipid profile	Yes	&	&	&	&	Yes	
On Atazanavir-containing ART	LFT	Yes	&	&	Yes	Yes	&	
	Lipid profile	Yes	&	&	Yes	Yes	&	
On Lopinavir-containing ART	Lipid profile	Yes	&	&	Yes	Yes	&	
	Blood sugar	Yes	&	&	Yes	Yes	&	
On Dolutegravir-containing ART	ALT (SGPT)	Yes	Yes	Yes	&	&	&	
	Blood sugar	Yes	Yes	Yes	&	&	&	

The prevalence of lipid abnormalities is notably high among patients on ART, especially those on Stavudine, Efavirenz, or boosted PIs. For these patients and those with significant risk factors for coronary artery disease, a fasting lipid profile should be conducted at 6 months or sooner if clinically indicated. Otherwise, annual evaluations are generally sufficient. This trend is expected to decrease with the use of Dolutegravir, which is not associated with significant lipid abnormalities.

Fasting blood sugar screening is recommended as part of the baseline assessment for all patients starting ART,

given that diabetes mellitus is a major cause of morbidity in India. More frequent visits or additional laboratory monitoring may be necessary if the patient experiences symptoms or side effects from ARVs or faces adherence challenges for any reason, including clinically indicated reasons as determined by the medical officer. Once the patient stabilizes, with improving CD4 counts, no opportunistic infections, and consistent adherence to ART for at least 6 months, the frequency of visits can be reduced to once every three months.^[16]



METHODOLOGY

Study Design: Prospective cohort

Sample Size: 40

Study Site: The study was conducted in the department of ART therapy, Outpatient Department (OPD) of Shri Mahant Indires Hospital, Uttarakhand.

Inclusion Criteria

- Patients willing to participate
- Age 18 years above
- Both gender male & female
- HIV Patient receiving ART therapy

Exclusion Criteria

- Patient not willing to participate

Data Collection methods: Patients were enrolled based on their willingness to participate. They were monitored monthly for their renal function markers, such as serum creatinine, estimated glomerular filtration rate (eGFR), proteinuria levels, and serum urea levels. Data was collected using a questionnaire approved by the Ethical Committee.

Statistical methods: For the statistical analysis, Posit's R Studio version 2024.12.1+563 was utilized. The Wilcoxon signed-rank test and the paired t-test were used to interpret the correlation. Additionally, the Shapiro-Wilk normalcy test was performed. R Studio and Microsoft Office Excel were used to construct graphical representations, and Microsoft Office Word was used to prepare tabulations. *eGFR was calculated by using eGFR calculator website of National kidney foundation https://www.kidney.org/professionals/gfr_calculator.

$$eGFR = 141 \times (S.cr/0.9)^{-0.411} \times (0.993 \text{ Age})$$

RESULT

DATA SHEET DEMOGRAPHIC DETAILS & RENAL BIOMARKERS VALUES OF PARTICIPANTS

Table. 9: Demographic details sheet

S.no	Age	Gender	Marital Status	Past Medical History	Social Habits	Food Habits	Physical Activity	Other Comorbidities	Address
1	58	Female	married	No	No	Both	No	Hepatitis	Dehradun
2	44	Male	married	No	Smoke	Vegetarian	Yes	Hepatitis	Dehradun
3	32	Male	married	No	Alcohol	Both	No	Hepatitis	Dehradun
4	34	Male	unmarried	Yes	Alcohol	Both	No	TB	Dehradun
5	22	Male	unmarried	No	Alcohol	Both	Yes	TB	Haridwar
6	39	Male	married	Yes	Alcohol	Vegetarian	No	TB	Dehradun
7	36	Male	married	Yes	Smoke	Both	No	Hepatitis	Dehradun
8	39	Male	married	No	No	Non Vegetarian	No	Hepatitis	Dehradun
9	45	Male	married	Yes	Smoke	Vegetarian	Yes	Hepatitis	Dehradun
10	30	Male	married	No	Smoke	Both	No	TB	Dehradun
11	31	Female	married	Yes	Alcohol	Both	Yes	TB	Dehradun
12	43	Male	married	Yes	Smoke	Both	No	TB	Tehri, Garhwal
13	45	Male	married	No	Alcohol	Both	Yes	Hepatitis	Tehri, Garhwal



14	32	Male	unmarried	Yes	Smoke	Both	No	Hepatitis	Dehradun
15	30	Male	married	No	Alcohol	Both	No	Hepatitis	Dehradun
16	24	Female	married	No	No	Both	No	TB	Dehradun
17	31	Male	married	Yes	No	Both	Yes	TB	Dehradun
18	31	Female	married	No	No	Both	No	TB	Dehradun
19	22	Male	unmarried	No	No	Both	Yes	Hepatitis	Haridwar
20	39	Male	divorced	No	Alcohol	Both	Yes	Hepatitis	Haridwar
21	39	Male	married	No	No	Both	No	Hepatitis	Haridwar
22	24	Male	married	No	No	Both	No	TB	Dehradun
23	26	Male	unmarried	No	Alcohol	Both	No	TB	Dehradun
24	31	Female	unmarried	Yes	No	Both	No	TB	Dehradun
25	32	Male	married	Yes	No	Both	No	Hepatitis	Tehri, Garhwal
26	28	Female	married	Yes	No	Both	No	Hepatitis	Haridwar
27	25	Male	divorced	No	No	Vegetarian	No	Hepatitis	Haridwar
28	33	Male	married	No	Alcohol	Both	Yes	TB	Dehradun
29	37	Male	married	Yes	No	Both	Yes	TB	Dehradun
30	23	Female	married	No	No	Both	Yes	TB	Dehradun
31	55	Female	married	No	No	Both	No	Hepatitis	Pauri Garhwal
32	46	Female	married	No	No	Both	No	Hepatitis	Pauri Garhwal
33	61	Male	married	Yes	Alcohol	Both	Yes	Hepatitis	Dehradun
34	38	Male	married	No	No	Vegetarian	No	TB	Dehradun
35	38	Male	unmarried	No	Tobacco	Vegetarian	No	TB	Haridwar
36	46	Female	married	Yes	No	Both	No	TB	Dehradun
37	68	Male	married	Yes	No	Vegetarian	No	Hepatitis	Dehradun
38	46	Male	married	Yes	Smoke	Both	Yes	Hepatitis	Dehradun
39	33	Female	married	No	No	Both	Yes	TB	Dehradun
40	43	Female	divorced	Yes	No	Both	Yes	TB	Haridwar

Table. 10: Renal biomarkers values sheet

S.no	Before S.Cretinine	After S.Cretinine	Before	After	Before Protein eGFR* Urea	After Protein eGFR* Urea	Before Serum Urea	After Serum Urea
1	0.9	1.1	74	58	210	310	15	25
2	1.1	1.2	85	76	140	159	20	28
3	1.2	1.5	82	63	152	165	20	32
4	0.8	0.9	119	115	130	145	12	15
5	1	1.3	109	80	139	158	18	20
6	1.3	1.6	72	56	205	312	30	33
7	0.7	0.8	122	118	102	138	10	15
8	1.5	1.7	60	52	314	388	35	34
9	1	1.1	95	84	116	164	17	20
10	0.9	1	118	104	119	131	16	18



11	1.4	1.5	52	47	316	344	28	31
12	1.2	1.4	77	64	158	198	24	30
13	0.6	0.7	121	116	115	144	8	15
14	1.1	1.2	91	82	124	177	19	24
15	1	1.1	104	93	98	115	17	22
16	1.3	1.4	59	54	287	338	27	29
17	0.8	0.9	121	117	127	144	14	15
18	1.6	1.8	44	38	755	895	33	37
19	1	1.1	109	97	109	142	22	26
20	0.9	1	111	98	75	112	15	20
21	1.2	1.3	79	72	155	164	20	24
22	1.4	1.5	72	66	157	177	29	33
23	0.7	0.8	130	125	99	132	11	15
24	1.1	1.2	69	62	166	210	21	25
25	1.3	1.4	75	68	194	265	25	29
26	0.8	0.9	103	89	101	129	13	19
27	1.5	1.6	66	61	117	164	27	31
28	1	1.1	102	91	90	141	20	24
29	0.9	1	113	99	106	144	18	21
30	1.2	1.3	65	59	215	365	22	27
31	1.4	1.5	44	41	898	1055	31	38
32	0.6	0.7	112	108	95	137	12	18
33	1.1	1.2	76	69	177	198	22	26
34	1.3	1.4	72	66	169	187	24	28
35	0.9	1.1	112	88	159	192	18	22
36	1	1.2	70	57	307	387	22	25
37	1.5	1.7	50	43	998	1145	34	38
38	1.2	1.3	76	69	149	164	24	28
39	0.8	0.9	100	87	195	177	16	21
40	1.1	1.2	64	58	224	368	22	27

*eGFR was calculated by using eGFR calculator website of National kidney foundation. $eGFR = 141 \times (S.cr/0.9) - 0.411 \times (0.993 \text{ Age})$

ANALYSIS OF DEMOGRAPHIC DETAILS

Table 11: Age of patients

The age group was 20-70 years, out of which 18 patients were in the 31-40 years age range, 10 patients were in the 20-30 years age range, 8 patients were in the 41-50 years age range, 2 patients were in the 61-70 years age range, and 2 patients were in the 51-60 years age range. (Figure. 1 & Table. 11)

21-30	10 (25%)
41-50	8 (20%)
61-70	2 (5%)
51-60	2 (5%)
Total	40 (100%)

Table 11: Data according to age group

Age	No. of patients (%)
31-40	18 (45%)

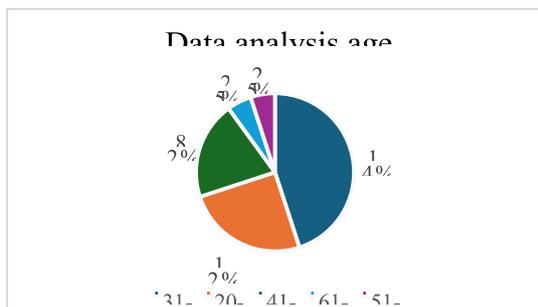


Figure 1: Data analysis according to age group

Table 12: Gender of patient's

The gender percentages of participants were 70% male and 30% female. Male patients comprised the majority of participants (70%), followed by female participants (30%). (Figure 2 & Table 12)

Table 12: Data according to Gender

Gender	No. of patients
Male	28 (70%)
Female	12 (30%)
Total	40 (100%)

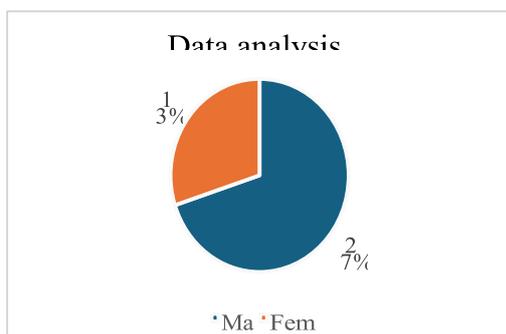


Figure 2: Data Analysis according to Gender

Table 13: Marital status of the patient's

Among the patients who participated, marital status was categorized into three groups: married, unmarried, and divorced. About 30 patients were married, 7 patients were unmarried, and 3 patients were divorced. (Figure 3 & Table 13)

Table 13: Data according to Marital Status

Marriage status	No. of patients
Married	30 (75%)
Unmarried	7 (17%)
Divorced	3 (8%)
Total	40 (100%)

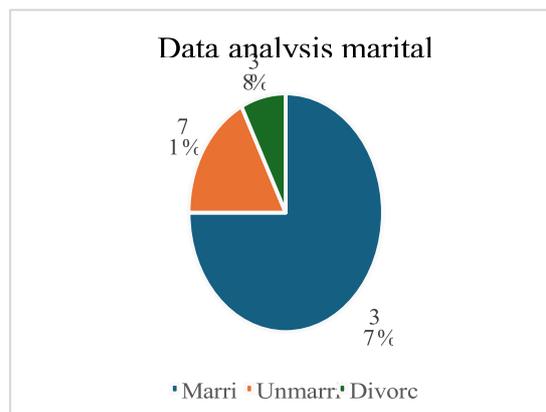


Figure 3: Data analysis's according to Marital Status

Table 14: Social habit

Among the patients who participated, social habits were categorized into four different groups: alcoholic, smoker, tobacco user, and none. Among them, 20 patients were not involved in any of these habits, 13 patients were alcoholic, 6 patients were smokers, and 1 patient used tobacco. (Figure 4 & Table 14)

Table 14: Data of participants according to social habits

Social habit	No. of patients
No	20 (50%)
Alcohol	13 (32%)
Smoke	6 (15%)
Tobacco	1 (3%)
Total	40 (100%)

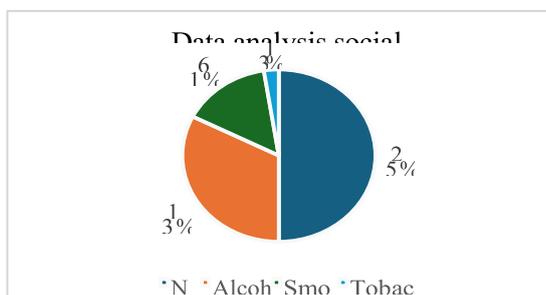


Figure 4: Data analysis according to social habits

Table 15: Food habits

Among the patients who participated, food habits were categorized into three different groups: vegetarian, non-vegetarian, and both. Among them, 31 patients were in the "both" category, 6 patients were vegetarian, and 3 patients were nonvegetarian. (Figure 5 & Table 15)

Table 15: Data of participants according to food habits

Food habit	No. of patient's
Both	31 (77%)
Vegetarian	6 (15%)
Non Vegetarian	3 (8%)
Total	40 (100%)

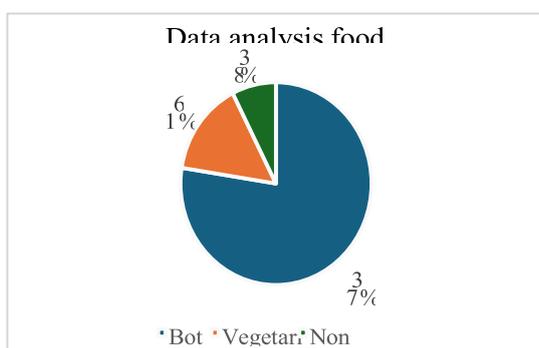


Figure 5: Data analysis according to food habits

Table 16: Physical activity

In the study, a total of 40 patients were assessed for their physical activity levels. Among them, 24 patients (60%) reported not engaging in physical activity, while 16 patients (40%) indicated that they were physically active. This distribution highlighted the varying levels of physical activity within the patient population.

(Figure 6 & Table 16)

Physical activity	No. of patients
No	24 (60%)
Yes	16 (40%)
Total	40 (100%)

Table 16: Data of participants according to physical activity

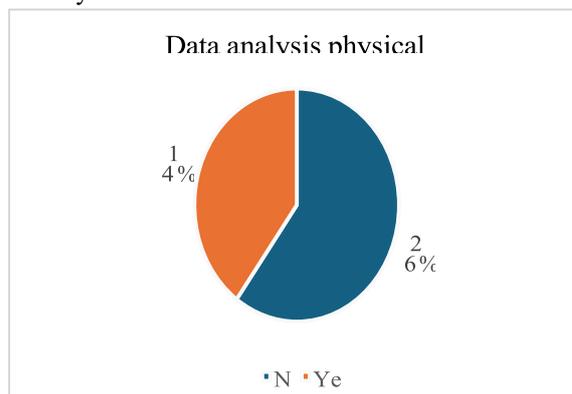


Figure 6: Data analysis according to physical activity

Table 17: Address of patients

In the study, a total of 40 patients were surveyed regarding their addresses. The majority of participants were from Dehradun, accounting for 27 patients (67%). Haridwar followed with 8 patients (20%), while Tehri, Garhwal contributed 3 patients (8%), and Pauri Garhwal had the least representation with 2 patients (5%). This distribution illustrated the geographic diversity of the patient population. (Figure 7 & Table 17)

Table 17: Data of participants according to address

Address	No. of patients
Dehradun	27 (67%)
Haridwar	8 (20%)
Tehri, Garhwal	3 (8%)
Pauri Garhwal	2 (5%)
Total	40 (100%)

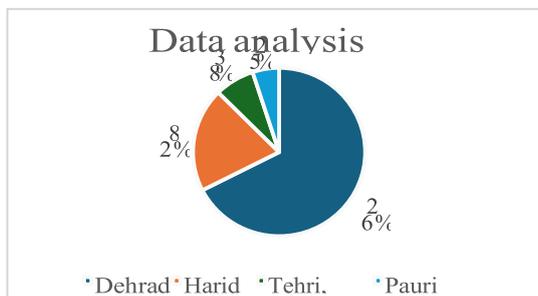


Figure 7: Data analysis according to address

ANALYSIS OF MEDICAL HISTORY COMORBIDITY'S & PRESCRIPTION PATTERN

Table 18: Past medical history

In the study, a total of 40 patients were evaluated for their past medical history. Out of these, 23 patients (57%) reported no significant past medical history, while 17 patients (43%) indicated that they had a relevant past medical history. (Figure 8 & Table 18)

Table 18: Data of participants according to past medical history

Past Medical History	No. of patients
No	23 (57%)
Yes	17 (43%)
Total	40 (100%)

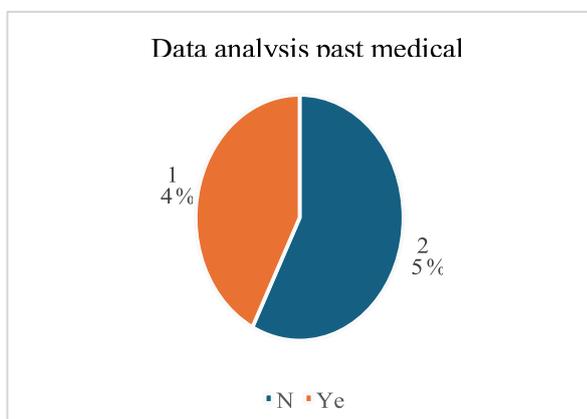


Figure 8: Data analysis according to past medical history

Table 19: Comorbidity

In the study, a total of 40 patients were assessed for other comorbidities. Among them, 20 patients (50%) were diagnosed with tuberculosis (T.B.), and an equal number, 20 patients (50%), had hepatitis. (Figure 9 & Table 19)

Table 19: Data of participants according to comorbidities

Other comorbidities	No. of Patient's
T.B	20 (50%)
Hepatitis	20 (50%)
Total	40 (100%)

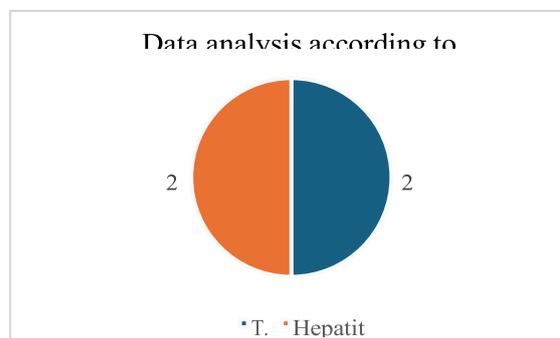


Figure 9: Data analysis according to comorbidities

Table 20: Prescription Pattern

In this study, patients diagnosed with HIV were evaluated for comorbid conditions, primarily Hepatitis and Tuberculosis (TB). For those with HIV and Hepatitis, the prescribed treatment included Sofosbuvir 400 mg and Velpatasvir 100 mg, alongside the antiretroviral regimen of Tenofovir disoproxil fumarate, Lamivudine, and Dolutegravir (300 mg/300 mg/50 mg). In patients with HIV and TB, the treatment regimen consisted of Rifampicin 150 mg, Isoniazid 75 mg, Ethambutol 275 mg, and Pyrazinamide 400 mg, in conjunction with the same antiretroviral therapy. This consistent approach highlighted the importance of effectively managing comorbid conditions in HIV patients to optimize treatment outcomes and enhance overall health management. (Figure 10 & Table 20)

**Table. 20:** Data sheet of prescription patterns

S.no	Disease condition	comorbid	Prescribing drug for comorbid	prescribed drug for HIVV condition
1	HIV	Hepatitis	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
2	HIV	Hepatitis	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
3	HIV	Hepatitis	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
4	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + Ethambutol 275 + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
5	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + Ethambutol 275 + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
6	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
7	HIV	Hepatitis	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
8	HIV	Hepatitis	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
9	HIV	Hepatitis	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
10	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + Ethambutol 275 + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
11	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir



				300mg/300mg/50mg
12	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
13	HIV	Hepatitis	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
14	HIV	Hepatitis	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
15	HIV	Hepatitis	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
16	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
17	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + Ethambutol 275 + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
18	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
19	HIV	Hepatitis	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
20	HIV	Hepatitis	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
21	HIV	Hepatitis C	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
22	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg



23	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
24	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
25	HIV	Hepatitis C	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
26	HIV	Hepatitis C	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
27	HIV	Hepatitis C	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
28	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + Ethambutol 275 + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
29	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
30	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
31	HIV	Hepatitis C	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
32	HIV	Hepatitis C	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
33	HIV	Hepatitis C	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
34	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir



				300mg/300mg/50mg
35	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + Ethambutol 275 + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
36	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
37	HIV	Hepatitis C	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
38	HIV	Hepatitis C	Sofosbuvir 400mg + Velpatasvir 100mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
39	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + Ethambutol 275 + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg
40	HIV	TB	Rifampicin 150mg + Isoniazid 75mg + pyrazinamide 400mg	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravir 300mg/300mg/50mg

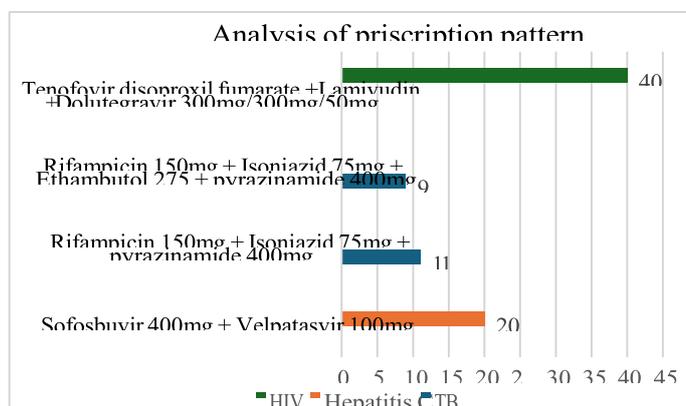


Figure 10: Analysis of prescription pattern

*Prescription is as per the national guidelines of the ART CO-RELATION BETWEEN RENAL BIOMARKERS VALUES AND ART DRUGS

Table 21: CO-RELATION BETWEEN TENOFOVIR DISOPROXIL FUMARATE +LAMIVUDIN +DOLUTEGRAVI AND SERUM CREATININE VALUES

The significance of serum creatinine (S. Creatinine) values before and after treatment with Tenofovir disoproxil fumarate, Lamivudine, and Dolutegravir was assessed in this study involving 40 patients. The results showed that before treatment, 13 patients had S. Creatinine values between 0.5-0.9 mg/dL, 26 patients had values between 1.0-1.5 mg/dL, and 1 patient had a value of 1.6 mg/dL or higher. After treatment, the numbers changed to 8 patients in the 0.5-0.9 mg/dL range, 27 patients in the 1.0-1.5 mg/dL range, and 5 patients with values of 1.6 mg/dL or higher. The significance value (p-value) for the overall change was less than 0.001, indicating a statistically significant difference. The paired t-test showed a mean median difference of 0.1325 with a p-value of less than 0.001,



while the Wilcoxon Signed-Rank test indicated a mean median difference of 0.1000 with a p-value of less than 0.001. These findings highlight the importance of monitoring renal function during treatment, as increases in S.Creatinine levels can indicate potential renal toxicity, necessitating careful assessment and management of kidney health.

Table 21: Co-relation between before and After Serum Creatinine with TLD drug

S. Creatinine value	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravi (TLD)		Significance value (p-value)
	Before	After	
0.5-0.9	13	8	<0.001
1.0-1.5	26	27	
>=1.6	1	5	
Total patients (N)	40	40	

Table 22: Statistical analysis tests

Test	Mean_Median_Difference	P .Value
Paired t-test	0.1325	< 0.001
Wilcoxon Signed-Rank	0.1000	< 0.001

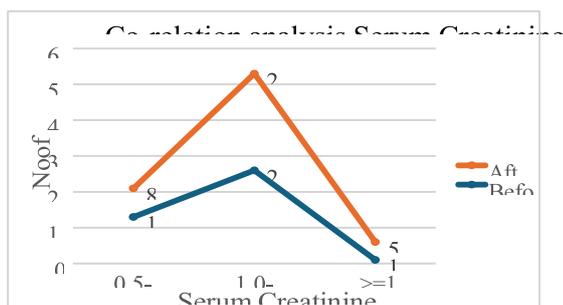


Figure. 11: Co-relation analysis Serum Creatinine values with TLD drugs

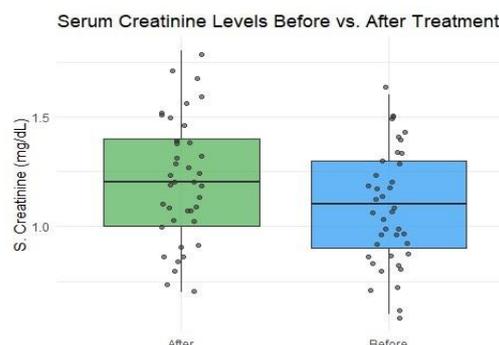


Figure.12: Individual patients S.creatinine changes

*Normal Range:

- Men: 0.6 to 1.2 mg/dL
- Women: 0.5 to 1.1 mg/dL

Table 23: CO-RELATION BETWEEN TENOFOVIR DISOPROXIL FUMARATE +LAMIVUDIN +DOLUTEGRAVI AND eGFR VALUES

This study assessed the estimated Glomerular Filtration Rate (eGFR) values before and after treatment with Tenofovir disoproxil fumarate, Lamivudine, and Dolutegravir (TLD) in a cohort of 40 patients. Before treatment, 2 patients had eGFR values between 30-44 mL/min, 3 patients had values between 45-59 mL/min, 17 patients had values between 60-90 mL/min, and 18 patients had values greater than 90 mL/min. After treatment, the distribution changed, with 3 patients in the 30-44 mL/min range, 8 patients in the 45-59 mL/min range, 17 patients remaining in the 60-90 mL/min range, and 12 patients with values greater than 90 mL/min. The significance value (p-value) for the overall change was less than 0.001, indicating a statistically significant difference. The Shapiro-Wilk normality test yielded a statistic of 0.8566 with a p-value of less than 0.001, suggesting that the data did not follow a normal distribution. The paired t-test showed a statistic of 10.7380 with a p-value of less than 0.001 and an effect size of -9.625, while the Wilcoxon Signed-Rank test produced a statistic of 820.0000 with a p-value of less than 0.001 and an effect size of -7.000. These findings underscore the importance of monitoring renal function, as changes in eGFR values can indicate potential renal impairment associated with the treatment regimen.

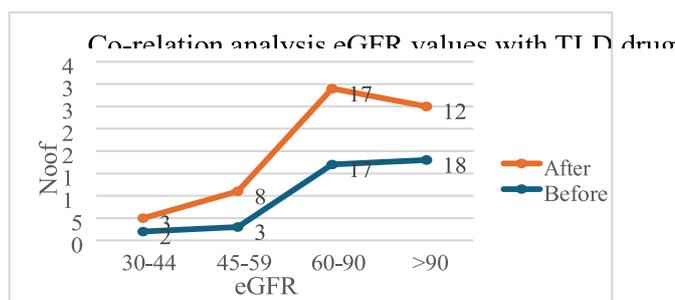
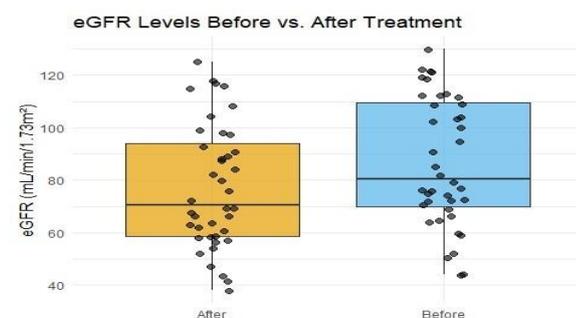
**Table 23:** Co-relation between Before and After eGFR with TLD drug

eGFR value	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravi (TLD)		Significance value (p-value)
	Before	After	
30-44	2	3	<0.001
45-59	3	8	
60-90	17	17	
>90	18	12	
Total patients (N)	40	40	

*Individual patient eGFR calculated value are available in Table no.10

Table 24: Statistical analysis tests

Test	Statistic	P value	Effect Size
Shapiro-Wilk Normality	0.8566	<0.001	NA
Paired t-test	10.7380	<0.001	-9.625
Wilcoxon Signed-Rank	820.0000	<0.001	-7.000

**Figure. 13:** Co-relation analysis eGFR values with TLD drug**Figure. 14:** Individual patient's eGFR values changes

*Normal Range: Greater than 90 mL/min/1.73 m²

Table 25: Co-relation between Tenofovir disoproxil fumarate +Lamivudin +Dolutegravi and proteinuria

The assessment of proteinuria values before and after treatment with Tenofovir disoproxil fumarate, Lamivudine, and Dolutegravir (TLD) was crucial for understanding renal health in patients. The data showed that among the 40 patients, 19 had proteinuria values of less than 150 mg/day before treatment, while 21 patients had values between 150-3000 mg/day. After treatment, the numbers changed to 14 patients with values less than 150 mg/day and 26 patients with values between 150-3000 mg/day. The significance value (p-value) for the overall change in proteinuria was 0.001, indicating a statistically significant difference. The Shapiro-Wilk normality test yielded a statistic of 0.8314 with a p-value of 0.001, suggesting that the data did not follow a normal distribution. The paired t-test showed a statistic of -7.1858 with a p-value of 0.001 and an effect size of 50.45, while the Wilcoxon Signed-Rank test produced a statistic of 8.5000 with a p-value of 0.001 and an effect size of 36.50. These findings indicated a significant increase in proteinuria levels after treatment, suggesting potential renal stress or damage



associated with the use of Tenofovir disoproxil fumarate, highlighting the importance of regular monitoring for early detection of renal

complications in patients undergoing this treatment regimen.

Table 25: Co-relation between before and after proteinuria with TLD drug

Proteinuria value (mg/day)	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravi (TLD)		Significance value (p-value)
	Before	After	
<150	19	14	0.001
150-3000	21	26	
Total patients (N)	40	40	

Table 26: Statistical analysis tests

Test	Statistic	P value	Effect Size
Shapiro-Wilk Normality	0.8314	0.001	NA
Paired t-test	-7.1858	0.001	50.45
Wilcoxon Signed-Rank	8.5000	0.001	36.50

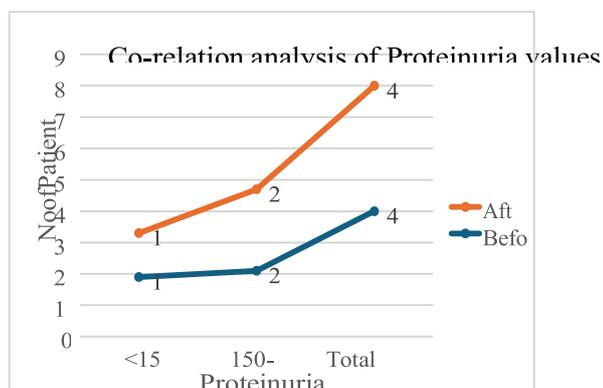


Figure. 15: Co-relation analysis of proteinuria values with TLD drug

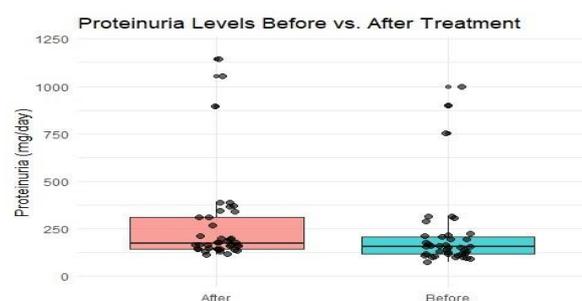


Figure. 16: Individual patients' proteinuria levels changes

*Normal Range: Less than 150 mg/day

Table 27: Co-relation between Tenofovir disoproxil fumarate +Lamivudin +Dolutegravi Serum Urea

The assessment of serum urea values before and after treatment with Tenofovir disoproxil fumarate, Lamivudine, and Dolutegravir was critical for evaluating renal function in patients. Among the 40 patients, 30 had normal serum urea levels (6-24 mg/dL) before treatment, while 10 patients had elevated levels (greater than 25 mg/dL). After treatment, the distribution changed significantly, with only 18 patients maintaining normal levels and 22 patients exhibiting high serum urea levels. The significance value (p-value) for the overall change was 0.000, indicating a statistically significant difference. The Shapiro-Wilk normality test yielded a statistic of 0.8931 with a p-value of 0.0012, suggesting that the data did not follow a normal distribution. The paired t-test showed a statistic of -12.4277 with a p-value of 0.0001 and an effect size of 4.425, while the Wilcoxon SignedRank test produced a statistic of 1.5000 with a p-value of 0.0001 and an effect size of 4.000. These findings indicate a significant increase in serum urea levels after treatment, suggesting potential renal stress or impairment associated with the use of Tenofovir disoproxil fumarate. This underscores the importance of regular monitoring of renal function to detect and manage potential complications in patients undergoing this treatment regimen.



Table 27: Co-relation between before and After Serum urea with TLD drug

Physical activity	No. of patients
No	24 (60%)
Yes	16 (40%)
Total	40 100%

Table 28: Statistical analysis tests

Serum urea value (mg/dl)	Tenofovir disoproxil fumarate +Lamivudin +Dolutegravi		Significance value (p-value)
	Before	After	
Normal (6-24)	30	18	0.000
High (>25)	10	22	
Total patients (N)	40	40	

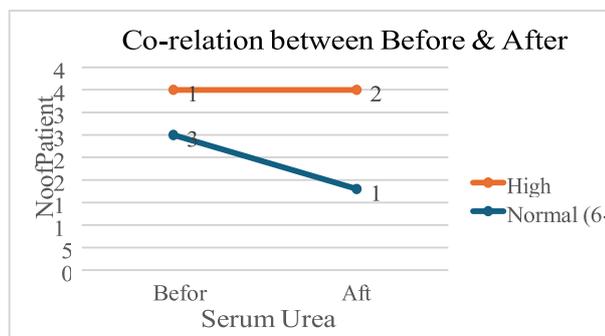


Figure. 17: Co-relation analysis of Serum urea with TLD drug



Figure. 18: Individual patient’s serum urea changes

*Normal Range: 6 to 24 mg/dL

DISCUSSION

This study aimed to assess the impact of antiretroviral therapy (ART) on renal function in HIV-infected patients. The results indicated significant changes in renal biomarkers, including serum creatinine, estimated Glomerular Filtration Rate (eGFR), proteinuria, and serum urea levels before and after the initiation of ART. These findings align with previous studies that have documented similar renal function alterations in HIV patients undergoing ART.^[17]

Demographic insights the patient population consisted of 40 individuals, predominantly male (70%) and married (75%). The age distribution showed a significant concentration in the 31-40 years age group, highlighting the demographic most affected by HIV in this study. This demographic trend is consistent with findings from Mcroft et al. (2010), which also reported a similar age distribution among HIV-infected patients. Renal function assessment serum creatinine levels study revealed a statistically significant increase in serum creatinine levels post-treatment, with a notable shift in the number of patients with elevated creatinine levels (≥ 1.6 mg/dL) from 1 to 5. This suggests a potential renal impairment associated with the ART regimen, particularly with Tenofovir disoproxil fumarate, which is known for its nephrotoxic potential. This finding corroborates the results of Friedman et al. (2014), who highlighted the



nephrotoxic effects of Tenofovir in their systematic review.^[16, 17]

The eGFR values also indicated a concerning trend, with an increase in patients falling into lower eGFR categories (30-44 mL/min and 45-59 mL/min) after treatment. This decline in renal function underscores the necessity for regular monitoring of kidney health in patients undergoing ART. Similar observations were made by Kumar et al. (2015), who reported significant declines in eGFR among HIV patients receiving ART. Proteinuria and Serum Urea: The increase in proteinuria levels from 19 patients with values <150 mg/day to 26 patients with values between 150-3000 mg/day posttreatment further emphasizes the renal stress induced by ART. Similarly, serum urea levels showed a significant rise, with a shift from 30 patients having normal levels to only 18 maintaining normal levels after treatment. This indicates a potential deterioration in renal function and highlights the importance of vigilant renal monitoring. These results are consistent with the findings of Brennan et al. (2016), who noted a correlation between ART and increased proteinuria in their cohort study.^[18, 19]

Comorbidities and their impact the presence of comorbidities such as tuberculosis (T.B.) and hepatitis among the patient population may complicate the renal effects of ART. The study found that 50% of patients had T.B. and an equal percentage had hepatitis, both of which can exacerbate renal issues. The treatment regimens for these comorbidities, combined with ART, may contribute to the observed renal function decline. This is supported by Rao et al. (2017), who discussed the compounded effects of comorbidities on renal health in HIV-infected individuals.^[20]

The findings of this study have significant clinical implications:

Monitoring: There is a critical need for regular renal function monitoring in HIVinfected patients receiving ART, particularly those on Tenofovir disoproxil fumarate. Early detection of renal impairment can lead to timely interventions to mitigate further damage. This recommendation aligns with the conclusions drawn by Gonzalez et al. (2018), who emphasized the importance of monitoring renal function in their meta-analysis. **Treatment Adjustments:** Clinicians may need to consider alternative ART regimens for patients with pre-existing

renal issues or those who exhibit signs of renal impairment during treatment. This is particularly relevant given the findings of Huang et al. (2019), which highlighted the need for careful selection of ART to minimize renal toxicity.^[21, 22] **Patient Education:** Educating patients about the potential renal side effects of ART and the importance of adherence to follow-up appointments for renal function tests is essential for optimizing patient outcomes. This aligns with Zhang et al. (2020), who advocated for patient awareness regarding the risks associated with specific ART regimens.^[23, 24]

CONCLUSION

Antiretroviral medication is essential for HIV management, but its effects on renal function cannot be disregarded. The substantial alterations in renal biomarkers found in this study emphasize the need for continued investigation and clinical monitoring to guarantee the security and effectiveness of HIV treatment plans. Future research should examine ways to reduce renal toxicity linked to ART and concentrate on long-term renal outcomes in HIV-infected patients.

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