

Determinants of Virologic Failure among HIV-Infected Patients Receiving Antiretroviral Therapy: A Cross-Sectional Study in Indonesia

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Abstract

Background Individuals with HIV who have compromised nutritional status are at a higher risk of contracting opportunistic infections due to weakened immunity, thereby contributing to increased viral load (VL) levels.

Objective To evaluate the prevalence and determinants of virologic failure in HIV/AIDS patients who had been on antiretroviral (ARV) therapy for at least 12 months.

Methods This study was carried out at an outpatient clinic at Tertiary Referral Hospital and two Public Health Centers from June to August 2023. The study included 74 patients aged 17 years or above who had been receiving ARV treatment for the past 12 months. The determinants evaluated in this research were gender, education, occupation, ARV initiation, ARV type, ARV therapy duration, body mass index, HIV-TB co-infection, and WHO clinical stage.

Results Among the 74 HIV patients included in the study, 35.1% experienced virologic failure. Several factors were found to be significantly associated with virologic failure, including age at antiretroviral (ARV) initiation ($P=.007$), body mass index (BMI) ($P<.001$), HIV-TB co-infection ($P=0.003$), World Health Organization (WHO) clinical stage ($P<.001$), and ARV treatment duration ($P=.014$). Multivariate analysis identified BMI ($P=.005$) and WHO clinical stage ($P=.001$) as the strongest predictors of virologic failure.

Conclusion This study concludes that low BMI and WHO clinical stage III/IV are significantly associated with virologic failure. Strengthening the immune system through improving nutritional status is crucial to achieve better virologic suppression in HIV patients receiving ARV therapy.

Keywords Virologic failure; Body mass index; WHO clinical stage; HIV/AIDS.

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Introduction

Virologic failure refers to the persistence of a plasma viral load exceeding 1000 copies/mL after 12 months of antiretroviral therapy, despite good medication adherence. Virologic failure is one of the

three criteria for treatment failure in human immunodeficiency virus (HIV) patients. Viral load testing is considered the gold standard for evaluating HIV patients receiving ARV therapy.^{1,2}

Despite the global attention to HIV infections, HIV

remains a major public health concern worldwide. According to the World Health Organization (WHO), approximately 40.8 million people were living with HIV globally in 2024, with an estimated 1.3 million new HIV infections reported during the same year.³ In Indonesia, the HIV burden also remains substantial, with an estimated 570,000 people living with HIV and persistent challenges in treatment coverage and viral suppression.⁴ Despite advances in antiretroviral therapy (ART), there are still a significant number of patients experiencing treatment failure, including virologic failure, which remains an important challenge in HIV management. Previous studies conducted in various countries have reported virologic failure rates ranging from 9% to 32%.^{1,2,5} Patients experiencing treatment failure are at a higher risk of mortality and morbidity. This emphasizes the need to monitor treatment progress and provide proper care for individuals with virologic failure, which is a clinical matter of concern.

Several studies have identified various factors associated with virologic failure in HIV patients, including gender, marital status, and body mass index (BMI).⁶ Additionally, clinical factors such as WHO clinical stage, HIV-TB co-infection, and CD4 cell count, as well as treatment-related factors like age at the initiation of first-line antiretroviral (ARV) therapy, treatment duration, and ARV adherence have been linked to virologic failure.⁶⁻¹⁰ However, the consistency and relative contribution of these determinants may vary across healthcare settings due to differences in nutritional status, tuberculosis burden, healthcare access, treatment monitoring capacity, and ARV implementation strategies. Moreover, in many resource-limited settings, routine virologic monitoring remains challenging, highlighting the importance of identifying simple

and clinically accessible predictors that may support early risk stratification for virologic failure. Although previous studies have reported several associated factors, evidence regarding determinants that remain independently associated with virologic failure in real-world clinical settings remains limited. Therefore, this study aimed to evaluate the prevalence and determinants of virologic failure among HIV/AIDS patients receiving ARV therapy and to identify clinically relevant predictors that may support early detection and management of treatment failure.

Methods

An observational cross-sectional study was conducted at the Voluntary Counselling and Testing (VCT) and Sexually Transmitted Disease (STD) Clinic of a tertiary referral hospital in Palembang, as well as at two affiliated Public Health Centers providing VCT and STD services. This study was approved by the Health Research Ethics Committee prior to study initiation under reference number No.DP.04.3/D.XVIII.6.11/ETIK/56/2023 dated 26.05.2023.

The inclusion criteria required participants to be HIV patients aged 17 years or older who had been receiving antiretroviral (ARV) therapy for at least 12 months. Patients with incomplete medical records were excluded from the study. Eligible subjects were asked to complete a questionnaire, and relevant data were obtained from medical records. Viral load was determined using polymerase chain reaction (PCR). The minimum sample size was calculated using the single-population proportion formula by Lemeshow *et al.* (1990). Given that the specific population proportion was unknown, $P=.50$ was adopted to ensure maximum sample size standard, resulting in a required minimum sample of 74 subjects. The study variables included demographic factors such as gender, education, and occupation, as well as clinical factors including body mass index (BMI), WHO clinical stage, HIV-TB co-infection, and treatment-related factors such as age at ARV initiation, ARV regimen, and ARV duration. The study's dependent

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variable was virologic failure, defined as a plasma viral load greater than 1,000 copies/mL following 12 months of ARV treatment. BMI status was categorized using the World Health Organization (WHO) Asia-Pacific guidelines into four groups: Underweight (<18.5 kg/m²), Normal weight (18.5–22.9 kg/m²), Overweight (23.0–24.9 kg/m²), and Obese (≥25.0 kg/m²).

Data collection was performed using a non-probability consecutive sampling technique, followed by statistical analysis. The data were analyzed using the Statistical Package for the Social Sciences (SPSS) Version 25.0 (IBM Corp., NY, USA). Results were presented as counts and percentages, while the Chi-square test was used for bivariate analysis. Furthermore, logistic regression was performed for multivariate analysis to determine the independent predictors for virologic failure.

Result

A total of 74 HIV-infected individuals were enrolled in this study. Among them, 51 (68.9%) were male. The majority had junior high school as their highest level of education (41.9%), and most participants were employed in the private sector (55.4%). Most participants were older than 26 years (66.2%) and had a BMI above 18.5 kg/m² (59.5%). A total of 49 subjects (66.2%) were classified as being in WHO clinical stages I/II. Additionally, 45.9% of participants were co-infected with tuberculosis (TB). The most prescribed antiretroviral therapy (ART) regimen was TLE (tenofovir, lamivudine, efavirenz), used by 70.3% of patients, with more than half (54.1%) receiving treatment for over 12 months. Based on the predefined operational definition, virologic failure was observed in 26 out of 74 patients (35.1%). The demographic and clinical characteristics of the study subjects are summarized in **Table 1**.

Bivariate analysis was conducted to assess the correlation between demographic and clinical characteristics in relation to virologic failure. The Pearson Chi-Square test found that several clinical

Table 1 Demographic and clinical characteristics of the study population (n=74).

Characteristic	n (%)
Gender	
Male	51 (68.9)
Female	23 (31.1)
Highest Education	
Elementary School	12 (16.2)
Junior High School	31 (41.9)
Senior High School	20 (27.0)
Bachelor's Degree	11 (14.9)
Occupation	
Laborer	19 (25.7)
Private Employee	41 (55.4)
Unemployed	14 (18.9)
Body Mass Index	
Underweight	30 (40.5)
Normal weight/overweight/obesity	44 (59.5)
WHO Clinical Stage	
Stage III/IV	25 (33.8)
Stage I/II	49 (66.2)
HIV-TB Co-infection	
Yes	34 (45.9)
No	40 (54.1)
ARV Type	
TLD	22 (29.7)
TLE	52 (70.3)
ARV initiation (age)	
17-25 years	25 (33.8)
≥ 26 years	49 (66.2)
ARV Therapy Duration	
12 months	34 (45.9)
>12 months	40 (54.1)
Virologic Failure	
Yes	26 (35.1)
No	48 (64.9)

characteristics were associated with virologic failure, including the age at ARV initiation (COR: 2.287, 95% CI: 1.252-4.175; p = 0.007), BMI (COR: 3.981, 95% CI: 1.915-8.276; P<.001), HIV-TB co-infection (COR: 2.647, 95% CI: 1.320-5.310; P=.003), WHO clinical stage (COR: 6.533, 95% CI: 3.011-14.178; P <.001), and duration of ARV (COR: 2.222, 95% CI: 1.141-4.326; P=.014), as shown in **Table 2**.

Multivariate analysis was performed using logistic regression, analyzing the age at ARV initiation, BMI, HIV-TB co-infection, WHO clinical stage, and duration of ARV. The results of the multivariate analysis found that the risk factors associated with virologic failure were BMI (AOR: 15.115; 95% CI: 2.308-99.006; P=.005) and WHO clinical stage

(AOR: 19.828; 95% CI: 3.628-108.351; P=.001) as displayed in **Table 3**.

Discussion

This study aimed to determine the prevalence and determinants associated with virologic failure in HIV/AIDS patients. The cross-sectional analysis revealed a virologic failure rate of 35.1% in the study population. This figure is nearly five times higher than the 7% reported in a 2017 study conducted across several Asian countries. One possible explanation for this discrepancy lies in the

differences in the study populations. Ross *et al.* focused their study exclusively on individuals who had received second-line antiretroviral therapy for a minimum duration of six months.¹¹ More recent data from sub-Saharan Africa indicate that virologic failure among patients on antiretroviral therapy remains substantial, with a pooled prevalence of approximately 16% in Ethiopia and country-level estimates ranging from about 11% in Uganda and Rwanda to over 30% in some settings such as Malawi and Tanzania.¹²

Bivariate analysis in this study identified five

Table 2 Relationship between demographic and clinical characteristics with virologic failure.

Variable	Virologic Failure n (%)		P-value*	COR	CI (95%)
	Virologic Failure	Non-Virologic Failure			
Highest Education					
Basic education	17 (32.5)	26 (60.5)	.350	1.362	0.702-2.643
Higher education	9 (29.0)	22 (71.0)			
Occupation					
Worker	21 (35.0)	39 (65.0)	.960	0.980	0.448-2.144
Unemployed	5 (35.7)	9 (64.3)			
Body Mass Index (BMI)					
Underweight	19 (63.3)	11 (36.7)	<.001	3.981	1.915-8.276
Normal weight/ overweight/obesity	7 (15.9)	37 (84.1)			
WHO Clinical Stage					
Stage III/IV	20 (80.0)	5 (20.0)	<.001	6.533	3.011-14.178
Stage I/II	6 (12.2)	43 (87.8)			
HIV-TB Co-infection					
Yes	18 (52.9)	16 (47.1)	.003	2.647	1.320-5.310
No	8 (20.0)	32 (80.0)			
ARV type					
TLD	10 (45.5)	12 (54.5)	.226	1.477	0.800-2.727
TLE	16 (30.8)	36 (69.2)			
ARV initiation (age)					
17-25 years	14 (56.0)	11 (44.0)	.007	2.287	1.252-4.175
≥26 years	12 (24.5)	37 (75.5)			
ARV Therapy Duration					
12 months	17 (50.0)	17 (50.0)	.014	2.222	1.141-4.326
>12 months	9 (22.5)	31 (77.5)			

*P-Value considered significant if <.05; COR: Crude; CI: Confidence Interval.

Table 3 Multivariate analysis results of the risk factors associated with virologic failure.

Variable	Beta Coefficient	SE	P-value*	AOR	CI (95%)
Body Mass Index (BMI)	2.716	0.959	.005	15.115	2.308-99.006
WHO Clinical Stage	2.987	0.866	.001	19.828	3.628-108.351
HIV-TB Co-infection	1.095	0.803	.173	2.990	0.620-14.427
ARV initiation (age)	1.003	0.971	.302	2.726	0.406-18.301
ARV Duration	1.602	0.863	.063	4.964	0.914-26.950

*P-Value considered significant if <.05; SE: Standard Error; AOR: Adjusted Odds Ratio.

variables significantly associated with virologic failure: body mass index (BMI), WHO clinical stage, HIV-TB co-infection, age at ARV initiation, and ARV duration. These findings align with previous research. Early initiation of ARV therapy, particularly in children and adolescents, has been linked to a higher risk of virologic failure.¹³ This may be due to riskier lifestyles, poor adherence, challenges in attending medical check-ups, financial constraints for routine monitoring, and fear of social stigma.¹⁴

HIV-TB co-infection was also found to be a significant risk factor for virologic failure. According to the findings, co-infection with HIV and tuberculosis was associated with a 2.647-fold greater likelihood of virologic failure. This finding is consistent with previous studies, which reported that the risk of virologic failure in HIV-TB co-infected patients ranges from 1.84 to 5.2 times higher.^{15,16} A 2025 retrospective cohort study of 148 adult TB/HIV co-infected patients reported that 24.3% experienced virologic failure during follow-up, with an incidence rate of 9.23 per 1,000 person-months.¹⁷ The increased risk is thought to be due to latent TB reactivation, new TB infections, or reinfection leading to active disease. Tuberculosis also accelerates HIV disease progression by promoting increased HIV viral replication and worsening immunosuppression, which is reflected in higher viral loads and more rapid CD4 T-cell decline in co-infected patients.^{18,19}

Another significant predictor of virologic failure was the duration of ARV treatment. Individuals receiving therapy for just 12 months faced a greater likelihood of failure than those on extended treatment regimens. This finding supports previous research demonstrating that longer ARV duration is associated with better viral suppression.¹⁵ A cross-sectional study found that after 14 months of ARV therapy, the viral suppression rate reached 91.5%. However, virologic failure related to therapy duration was not directly linked to treatment adherence.^{10,15}

BMI emerged as a key risk factor for virologic failure in both bivariate and multivariate analyses. In this study, 30 participants (40.5%) were classified as underweight. Those with a low BMI had a 15.115-fold higher risk of virologic failure. Ahmed *et al.* similarly observed that patients with a body mass index under 16 kg/m² were 4.2 times more likely to experience virologic failure, supporting the present finding.⁹ Similarly, a cross-sectional study by Negash found that HIV patients with underweight BMI had a 2.1 times greater risk of virologic failure.¹⁶

Virologic failure is strongly associated with the clinical condition of patients, including their nutritional status. Good nutritional status enhances the immune function of HIV patients, reduces clinical deterioration, improves quality of life, and prevents mortality. Some researchers have found that poor nutritional status disrupts processes such as phagocytosis and complement activity, leading to clearance problems with pathogens. Poor nutritional status also affects adaptive immunity in HIV patients, causing lymphoid organ atrophy, decreased IgA expression in saliva and tears, decreased circulating B cells, hindered hypersensitivity responses, and a shift from Th1 to Th2 responses. Consequently, HIV patients with poor nutritional status have a higher risk of opportunistic infections.²⁰

Most of the study population consisted of patients in clinical stages I/II (66.2%), while those in stages III/IV experienced virologic failure (80%). Multivariate analysis found that patients in clinical stages III/IV had a 19.828-fold higher risk for virologic failure. Previous studies have found that HIV patients in clinical stages III and IV have a risk 1.73 to 3.3 times higher for virologic failure.^{15,21} The increased risk of virologic failure in patients with clinical stages III/IV is related to their immunity. Patient immunity is closely linked to CD4 cell counts and viral load levels, which are influenced by the presence of opportunistic infections.^{17,18,22}

Additionally, the use of combination therapy in HIV patients with opportunistic infections is associated with increased drug toxicity. Drug toxicity can weaken immune function, thereby increasing the risk of viral replication and virologic failure.^{17,18,22}

However, this study still has some limitations. One of them is that it did not evaluate treatment adherence and CD4 cell counts in patients.^{9,10} Additionally, the study did not consider the presence of other co-infections that could occur in patients, given that one in three subjects had clinical stages III/IV.

Conclusion

In conclusion, 35.1% of HIV/AIDS patients who had been on antiretroviral therapy for a minimum of 12 months experienced virologic failure. This study identified low body mass index (BMI) and WHO clinical stage III/IV as significant risk factors associated with virologic failure. Improving nutritional status through targeted education and support is crucial for enhancing immune function and promoting effective viral suppression in individuals living with HIV/AIDS.

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Declaration of patient consent Authors certify that they have obtained all appropriate patient consent.

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Author's contribution

F, RS, MIHP: Substantial contributions to study design, acquisition of data and manuscript writing.

EB,RC,SD,SB: Substantial contributions to analysis and interpretation of data and critical review of the manuscript.

Every author has given final approval of the manuscript version to be published and agreed to be accountable for all aspects of the work.

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