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Evaluation of Antiretroviral and Tuberculosis Therapy Based on Clinical Outcomes in Patients With HIV/AIDS and Tuberculosis Co-Infection at Regional General Hospital in Denpasar

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ABSTRACT

Human immunodeficiency virus and tuberculosis (HIV-TB) co-infection presents a significant challenge in Denpasar due to high incidence and complex treatment. This retrospective single-cohort study aimed to analyze the relationship between the results of therapy evaluation and the clinical outcomes in patients with HIV-TB. Secondary data from 20 HIV-TB treatment at a Regional General Hospital in Denpasar during 2022-2024 were evaluated. Fisher's Exact test was performed to analyze the association between adherence to antiretroviral therapy (ART) and antituberculosis therapy (ATT), as per the guidelines, and their treatment success. Results showed predominance in males of productive age (60%), with cough as the most common symptom (75%), and 80% patients at HIV stage 4. All patients (N=20) received first-line ART and ATT. However, only 20% completed the treatment algorithm and 40% achieved treatment success. Although no significant association was found between treatment evaluation and success (p = 0.101), the relevant findings in this study emphasized the important role of rational drug use based on guidelines. Further studies with larger samples and a prospective approach are needed to explore additional factors affecting clinical outcomes of patients with HIV-TB undergoing therapy according to the established guidelines.

INTRODUCTION

Human immunodeficiency virus/ acquired immunodeficiency syndrome (HIV/AIDS) continues to be a major health issue worldwide. HIV/AIDS is often complicated by opportunistic infections such as tuberculosis (TB). TB contributes to mortality among people living with HIV (PLHIV), particularly in developing countries. In 2022, an estimated 6,500 deaths from HIV/AIDS and TB (HIV-TB) co-infection were reported in Indonesia (Ministry of Health of the Republic of Indonesia, 2023). In Denpasar, most HIV-TB patients were in advanced clinical stages (Rebecca et al., 2021).

Management of HIV-TB requires both antiretroviral therapy (ART) and anti-tuberculosis treatment (ATT). While ART improves immune function and reduces HIV-related morbidity, ATT eradicates *Mycobacterium tuberculosis*. However, challenges remain including drug–drug interactions, hepatotoxicity, and immune reconstitution inflammatory syndrome (IRIS). These also include the delayed treatment initiation and adherence issues due to long-term therapy (Patel et al., 2024).

Previous studies highlighted the importance of adherence and rational drug use in determining treatment success in HIV-TB co-

infection. On the one hand, patients' adherence was the ultimate factor affecting treatment success. On the other hand, however, inappropriate medication use of ATT remains (Putri et al., 2024; Rakhmandani et al., 2024). Guidelines from the World Health Organization (WHO) and the government of Indonesia emphasize the integrated and guideline-based management to optimize outcomes of HIV-TB co-infection (Ministry of Health of the Republic of Indonesia, 2023; WHO, 2016, 2025)

Nevertheless, the previous studies had not comprehensively evaluated the medication in accordance with the available guidelines. This study aimed to identify the relationship between the results of therapy evaluation and the clinical outcomes in HIV-TB patients at a regional general hospital in Denpasar, based on the treatment adherence to national and WHO guidelines. The established treatment guidelines are certainly providing measurable monitoring parameters and supporting evidence-based medicine practice for improving optimal therapy outcomes.

METHODS

Research Design

This study was an analytic-quantitative research with a single-cohort design. Analytic quantitative research aims to examine relationships or causal effects between variables using numerical data and statistical analysis (Nurita Andayani, 2023). Evaluation in this study referred to guidelines by the WHO (2016) and the Ministry of Health, Republic of Indonesia (Ministry of Health of the Republic of Indonesia, 2023; WHO, 2016). Evaluation aspects included the adherence to the algorithm (*timeline* of starting ARV within 2-8 weeks after ATT, duration of ATT for at least 9 months, and schedule punctuality of diagnosis and sensitivity tests) and medication profiles in the referred guideline (standard regimens of ATT and ART). Treatment success was defined as outcomes of tuberculosis and HIV at the end of cohort observation, such as symptoms improvement and laboratory test results. The data used were measurable parameters, such as viral load suppression <40 copies/ml and negative acid-fast bacilli (AFB) smear results. This research was granted permission with number 000.9.2/1060/RSUDW and ethical clearance with number 000.9.2/1970/RSUDW from the research location hospital.

Time and Place of Study

The study was conducted from November 2024 to July 2025 at a Regional General Hospital in Denpasar. According to the Bali Provincial Data Center (2024–2025), Denpasar City remains recorded as the area with the highest number of HIV/AIDS cases in Bali Province. Regional General Hospital is a referral hospital in Denpasar that provides care for HIV/AIDS and TB patients, including those with co-infection. The hospital receives approximately 70 to 120 HIV/AIDS patient visits per day, including new patients, follow-up patients, and counseling services.

Population and Sample

The study population consisted of outpatient HIV/AIDS patients at a regional public hospital in Denpasar City who met the following characteristics. Inclusion criteria consisted of patients diagnosed with HIV/AIDS with active TB co-infection during January 2022- December 2024, patients with accessible medical records (patient identity and medical history), age 18-59 years, and patients who completed ATT until the end of recorded TB treatment. Exclusion criteria were patients with severe comorbidities that could affect treatment outcomes (e.g., cancer, end-stage renal failure), patients referred to other healthcare facilities, and patients who died during treatment. From a total of 39 potential cases, only 20 patients met the specified criteria. To provide a comprehensive description despite the limited sample, the entire qualified population was included to represent the intended data collection.

Data Analysis

Data were analyzed descriptively and inferentially. Treatment evaluation was assessed based on therapeutic algorithms, drug appropriateness, dosage, and patient suitability, and shown in tables. Data were classified into appropriate/ inappropriate and controlled/ uncontrolled categories, then expressed as percentages. The relationship between

treatment evaluation and treatment success was analyzed using Fisher's Exact test (95%).

RESULT AND DISCUSSION

Patient Demographic Characteristics

Table 1. Patient characteristics

Categori (N=20)	n (%)
Gender	
Male	12 (60)
Female	8 (40)
Age	
21-30 years	5 (25)
31-40 years	6 (30)
41-50 years	3 (15)
51-60 years	5 (25)
>60 years	1 (5)
Occupation	
Private employee	14 (70)
Entrepreneur / Self-employed	1 (5)
Unemployed	5 (25)
Symptoms and signs	
Cough	15 (75%)
Weak	8 (40%)
Body weight loss	7 (35%)
Fever	5 (25%)
Congested	3 (15%)
Nauseous	1 (5%)
Initial AFB Results	20 (100%)
Initial VL Results	20 (100%)
TB Type	
TB SO	20 (100%)
TB RO	0 (0%)
HIV/AIDS stages	
Stage 3	4 (20%)
Stage 4	16 (80%)

Note: n: number of patient groups, %: percentage of patients; AFB: acid-fast bacilli; VL: viral load; SO: drug sensitive; RO: drug resistant

Observation of patient demographic characteristics (Table 1, N=20) showed that TB-HIV co-infection was most prevalent among males aged 31–40 years, with the majority working as private employees.

This productive age group is particularly vulnerable due to high mobility, broad social interactions, and occupational exposure (WHO, 2021). Men in this age range are also more likely to engage in risk behaviors such as smoking and irregular health screening, further increasing susceptibility (Ministry of Health of the Republic of Indonesia, 2023).

The predominance among private employees may be linked to workplace-related stress, crowded environments, and irregular schedules that hinder access to preventive health services (Corrente et al., 2024). Socioeconomic factors, including limited health insurance coverage compared to civil servants or state-owned company employees, also contribute to delayed TB-HIV management (Ajmala & Wulandari, 2015; Dheda et al., 2022). These findings highlight the need for workplace-based interventions, such as regular health screening, TB-HIV education, and stronger collaboration between companies and public health authorities to reach this high-risk population.

Patients' Clinical and Treatment Profile

Clinical observations (**Table 1**) demonstrated that most patients presented with advanced HIV stage (3–4), marked by immunosuppression, elevated VL, and severe symptoms such as weight loss, persistent cough, fever, nausea, and dyspnea. The most common symptoms were consistent with the pathophysiology of TB-HIV, where immunosuppression worsens Mycobacterium tuberculosis infection (Dheda et al., 2022; Ministry of Health of the Republic of Indonesia, 2023; WHO, 2021). Positive baseline AFB in all patients indicated high bacterial burden and transmissibility, while all patients with detected VL reflecting poor virologic control. Pulmonary TB was predominant, aligning with national HIV-TB co-infection epidemiology. The majority were in stage 4 (AIDS), highlighting late diagnosis and treatment initiation. The treatment profile (**Table 2**) showed that all patients received the first-line TB regimen 2 months of isoniazid, rifampicin, pyrazinamide, ethambutol followed by 4 months of Isoniazid and ethambutol (2HRZE/4HR), with dosage adjusted based on body weight. However, treatment duration varied from the standard 6-month course, suggesting variability in adherence or clinical response. For HIV, 80% received first-line ART; tenofovir, lamivudine, dolutegravir (TLD) once daily, while the rest also received additional dolutegravir (DTG). Although daily dosing supported adherence, varied ART initiation might be due to severe immunosuppression (early initiation) or may reflect clinical concerns over IRIS (delayed initiation). Such delays are associated with increased mortality up to 30% (Dheda et al., 2022; Sitepu et al., 2024).

Table 2. Patient treatment profile

Category (N=20)	n (%)
Types of ATT Drugs	
Category 1 (2HRZE/4HR)	20 (100)
Types of ARV Drugs	
TLD	16 (80)
TLD+DTG (50)	4 (20)
Dosage and frequency of ATT	
3 tablets once daily	4 (20)
4 tablets once daily	9 (45)
5 tablets once daily	7 (35)
ART Dosage and Frequency	
1 TLD tablet once daily	16 (80)
1 TLD tablet once daily + DTG	4 (20)
ATT Duration (Months)	
4	1 (5)
5	6 (25)
6	9 (45)
7	1 (5)
9	3 (15)
ART initiation Timeline (Weeks) after OAT	
1	4 (20)
2	6 (30)
3	5 (25)
4	2 (10)
10	1 (5)
12	1 (5)
16	1 (5)

Note: ART: antiretroviral therapy; ATT: anti-tuberculosis treatment; HRZE: rifampicin 150 mg, isoniazid 75 mg, pyrazinamide 400 mg, ethambutol 275 mg; TLD: tenofovir, lamivudine, dolutegravir; DTG: dolutegravir; OD: once daily

These findings indicate suboptimal alignment with WHO and national guidelines, reflecting barriers such as late diagnosis, limited access to CD_4/VL monitoring, clinical hesitancy, and health system discrepancy. Integrated TB-HIV management, timely therapy initiation, and patient adherence support remain essential to optimize outcomes (Ministry of Health of the Republic of Indonesia, 2023; WHO, 2016, 2025).

Treatment Evaluation Results

The evaluation of ARV and ATT are shown in **Table 3**, **Table 4** and **Table 5**. Findings indicate that almost half of the patients received ATT within the recommended timeline according to the guidelines. However, inconsistencies in treatment initiation remain, reflecting challenges in adherence to both national (Ministry of Health of the Republic of Indonesia, 2023; WHO, 2021) recommendations.

All patients underwent Xpert MTB/RIF and routine AFB examinations, confirming the adequacy of TB diagnostic procedures. Nevertheless, only small number of patients fully adhered to the complete therapeutic algorithm, which includes the timely initiation of ATT and ART, molecular testing, and regular bacteriological monitoring. This low adherence highlighted the need for strengthening integrated HIV–TB services. Studies from South Africa have similarly reported that delays in either ARV initiation or TB diagnostics increased treatment failure and mortality (Moyo et al., 2023)

Table 3. Evaluation of therapy

Categori (N=20)	Appropriate	Not Appropriate
Evaluation based on therapy algorithm		
ATT Timeline Aspect	9 (45%)	11 (55%)
ARV Timeline Aspect	11 (55%)	9 (45%)
Xpert MTB/Rif Procedure Aspect	20 (100%)	0 (0%)
Supporting Examination (LPA) Aspect	20 (100%)	0 (0%)
Periodic AFB Examination Aspect	20 (100%)	0 (0%)
Total evaluation based on therapy algorithm	4 (20%)	16 (80%)
Category (N=20)	**Correct**	**Not Correct**
Type of ATT	20 (100%)	0 (0%)
Type of ARV	20 (100%)	0 (0%)
Total evaluation based on treatment profile	20 (100%)	0 (0%)

Note: AFB: acid-fast bacilli; ATT: anti-tuberculosis drugs; ARV: antiretroviral; LPA: Line Probe Assay, MTB/Rif: *Mycobacterium tuberculosis*/Rifampicin

Table 4. Evaluation of clinical outcomes of TB and HIV/AIDS

Category (N=20)	Achieved	Not achieved
Evaluation of TB clinical outcomes		
Symptom improvement	20 (100%)	0 (0%)
AFB results	9 (45%)	11 (55%)
HIV/AIDS Treatment Profile Evaluation		
Symptom improvement	20 (100%)	0 (100%)
VL Results	20 (100%)	0 (100%)

Note: AFB: acid-fast bacilli; Description: VL: viral load

Table 5. Relationship between treatment evaluation and clinical outcomes

Evaluation categories (N=20)		Comprehensive therapy success	
		Achieved	Not achieved
Comprehensive evaluation	**Correct**	3 (15%)	1 (5%)
	Incorrect	4 (20%)	12 (60%)
	p-*value**	0.101	

Description: N: total number of patients; p-value: (<0.05: there is a significant difference, >0.05: there is no significant difference; *: Fisher Exact non-parametric statistical analysis with a 95% confidence level

Additional DTG on the use of first line ART in some patients (**Table 2**) might have affected their clinical outcomes. Although guidelines recommend DTG 50 mg twice daily when co-administered with rifampicin due to drug–drug interactions, most patients continued standard once-daily dosing. Clinical trials, however, indicated no significant difference in short-term virologic outcomes between once- and twice-daily dosing (Griesel et al., 2023). The uneven implementation of dose adjustments in this study suggested gaps in drug availability, provider training, and guideline dissemination.

These findings emphasize the importance of consistent application of therapeutic algorithms, integrated services, and continuous education of healthcare providers to ensure optimal HIV–TB treatment outcomes.

Changes in Clinical Outcome Assessment

Clinical outcome changes in HIV-TB patients are presented in **Tables 4** and **Table 5**. Although all patients experienced clinical improvements with no remaining symptoms, 45% of them achieved negative AFB conversion (**Table 4**). This discrepancy between symptom improvement and bacteriological conversion is concerning, as negative AFB results are key indicators of microbiological cure. Normally, conversion is expected by the 2nd–3rd month. Persistence at the sixth month might suggest issues with treatment adherence, drug interactions, resistance, or comorbid HIV-related immunosuppression (Ministry of Health of the Republic of Indonesia, 2023; WHO, 2021). Prior studies confirm that non-adherence due to lengthy treatment regimens has contributed significantly to poor outcomes (Abdu & Walelgn, 2021; Alipanah et al., 2018; Lee et al., 2024).

HIV–TB co-infection is known to delay sputum conversion due to immune suppression and possible drug–drug interactions between ATT and ARV (Tadesse et al., 2022). Additional factors include late initiation of therapy, poor adherence, and lack of regular monitoring. These findings emphasized the importance of ongoing clinical and microbiological evaluation, along with strategies to improve adherence, strengthen patient education, and assess potential drug resistance (Corrente et al., 2024; Tesfahuneygn et al., 2015).

For HIV outcomes (**Table 4**), all patients achieved clinical improvement. Achieving viral suppression aligns with the WHO principle "u=u" (undetectable = untransmittable), which highlights treatment success in both patient health and transmission prevention (Ministry of Health of the Republic of Indonesia, 2023; WHO,

2021). VL monitoring at six months and annually thereafter remains a cornerstone of evaluating treatment success. The use of first-line TLD has contributed significantly to these results, consistent with evidence showing high efficacy and strong resistance barriers of dolutegravir-based regimens (Boyd et al., 2021) Full adherence further underscored the importance of effective counseling, psychosocial support, and reliable drug access (Bisara Lolong et al., 2019; Patel et al., 2024).

Relationship Analysis of Treatment Outcomes Based on Therapy Evaluation

Fisher's Exact test (**Table 5**) revealed no statistically significant association between comprehensive therapy evaluation and treatment success ($p = 0.101$). Only 15% of patients undergoing complete evaluation achieved treatment success, while 20% of those without proper evaluation still succeeded. This lack of association may be explained by small sample size, multifactorial determinants of treatment outcome (e.g., adherence, immune status, comorbidities, social support), and limited follow-up interventions after evaluation.

Although not statistically significant, the findings in this study remained relevant and highlighted the need for comprehensive therapy evaluation in daily practice. Considering small sample size and retrospective design in this study, larger prospective studies are recommended to confirm these findings and to explore additional factors influencing treatment success (Boyd et al., 2021; Gupta-Wright et al., 2024).

CONCLUSIONS

The treatment in HIV-TB co-infected patients in this study was not completely aligned with the national and WHO guidelines, with only a minority following the complete algorithm (20%). While ART achieved 100% viral load suppression, TB outcomes were suboptimal due to a low rate of the targeted AFB smear test results. This study reported that the relationship between therapy evaluation results and the clinical outcomes in HIV-TB patients was not significantly meaningful, based on the established guidelines ($p = 0.101$).

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AUTHORS' CONTRIBUTIONS

Kurnianta PDM was responsible for conceptualization, methodology, validation, formal analysis, writing (drafting, reviewing, editing), and supervision. Suwirtawati NPD was responsible for data collection, data curation, formal analysis, and writing (draft, editing). Dhrik M was in charge of validation and writing (reviewing).

CONFLICT OF INTERESTS

The authors declared that no conflict of interest could affect the integrity of this research.

ETHICAL CONSIDERATION

The authors had followed the ethical conduct during the research process, and ethical clearance had been granted by one of the Regional General Hospitals, Denpasar (number 000.9.2/1970/RSUDW)

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