



PREDICTING UNFAVORABLE TREATMENT OUTCOMES IN MULTI-DRUG RESISTANCE TUBERCULOSIS PATIENTS: A RETROSPECTIVE STUDY IN JAKARTA, INDONESIA

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ABSTRACT

Treatment of multidrug-resistant tuberculosis (MDR-TB) with a short-term regimen offers promise in terms of higher effectiveness and reduced therapy duration. However, treatment failure remains a major challenge in its implementation. This study aimed to identify predictive factors associated with unfavorable treatment outcome (UTO) among MDR-TB patients receiving the short-term regimen in DKI Jakarta Province from 2020 to 2022. Methods: A retrospective cohort study, using data from the National TB Information System (SITB). We retrieved all MDR-TB patients who started short-term treatment regimens at referral hospitals in DKI Jakarta Province in the period January 2020 to December 2022, totaling 166 patients. Each patient was followed for up to 11 months from the initiation of treatment, with final treatment outcomes collected through November 2023. Survival analysis using Cox proportional hazards regression was employed to assess the association between patient characteristics and time to UTO. Results: A total of 43.4% of patients is UTO. The cumulative probability of remaining free from UTO was 38% after day 400. Multivariate regression analysis showed that HIV-positive status (aHR = 2.98; 95% CI: 1.77–4.99) and comorbid diabetes mellitus (aHR = 1.92; 95% CI: 1.19–3.11) were significantly associated with an increased risk of UTO. Conclusion: UTO among MDR-TB patients on the short-term regimen remains high. HIV status and diabetes comorbidity are critical factors influencing treatment outcomes and should be prioritized in clinical management strategies for MDR-TB.

Keywords: multidrug resistant; short-term regimen; tuberculosis; unfavorable treatment outcome

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INTRODUCTION

Multidrug-resistant tuberculosis (MDR-TB) is a TB disease caused by strains of *Mycobacterium tuberculosis* that are resistant to first-line anti-tuberculosis drugs (OAT), namely rifampicin and isoniazid (World Health Organization, 2022a). The development of MDR-TB is often associated with inadequate treatment management including inappropriate use of TB drugs, poor drug quality, unsafe storage, and premature discontinuation of treatment. This not only increases drug resistance but also encourages transmission between individuals (Kementerian Kesehatan RI, 2024). As a consequence, MDR-TB poses a major challenge to global TB control, characterized by lower treatment success rates than drug-sensitive TB and a higher risk of death. MDR-TB treatment has previously relied on long-term regimens with a duration of 18-20 months. However, these regimens faced various obstacles, such as high costs, severe side effects, and low patient adherence (Trébucq et al., 2020; World Health Organization, 2022b). In response, the WHO in 2020 recommended the use of short-term regimens with a duration of 9-11 months as the new standard of care for most MDR-TB patients. These regimens are expected to increase adherence, reduce costs, and improve treatment outcomes (World Health Organization, 2022b). Long-term regimens are maintained for patients with additional resistance to fluoroquinolones or specific clinical conditions

(Kementerian Kesehatan RI, 2024).

In Indonesia, the country with the third highest MDR-TB burden globally, notification of new MDR/RR TB cases in 2020 is estimated to reach only 32%. Treatment initiation rates are also still low, at only 58% of those identified, accompanied by a downward trend in treatment success rates and an increase in dropout rates and deaths. This figure shows that the results are still far below the national target of 80%. (Kementerian Kesehatan RI, 2020). This treatment failure rate warrants special attention as it threatens the TB elimination program target of 2030. Previous studies have shown that factors such as advanced age, HIV-positive status, comorbid diabetes mellitus (DM), poor nutritional status, and delayed treatment initiation contribute to poor MDR-TB treatment outcomes (Alemu et al., 2021; Gayoso et al., 2018; Htun et al., 2018; Xu et al., 2023). On the other hand, the effectiveness of short treatment regimens in reducing treatment failure and mortality is variable. A study in Tanzania showed that patients on short treatment regimens had a higher risk of death than those on long-term regimens (Myemba et al., 2021), while a study in Pakistan identified age, low body mass index, and previous history of TB as significant determinants of treatment failure in short treatment regimens (Wahid et al., 2021). Although a number of risk factors have been identified in global studies, evidence regarding the determinants of UTO in patient MDR-TB on short-course regimens in DKI Jakarta is limited. Therefore, this study was designed to identify predictive factors associated with unfavorable treatment outcome (UTO) in patients with MDR-TB on short-term regimens in DKI Jakarta Province in 2020-2022.

METHOD

This study is a quantitative study with a retrospective cohort research design. The data from the Indonesian Ministry of Health's Tuberculosis Information System (SITB), which is a cohort of registration data for MDR-TB patients starting from diagnosis until they have treatment results. The population in this study were all confirmed MDR-TB patients who started treatment at the TB treatment referral hospital in DKI Jakarta Province and were recorded in SITB Indonesia data in the period January 2020 - December 2022, and were observed for 11 months. The sample used in this study was 166 patients who met the inclusion and exclusion criteria. Inclusion criteria were patients aged ≥ 15 years with a confirmed diagnosis of MDR-TB and had treatment results during the observation period until November 2023. Exclusion criteria were extra-pulmonary TB patients and patients who had incomplete case data on diagnosis date, treatment start date, treatment outcome date, and treatment outcome status. The sampling technique in this study used total sampling. The diagnosis of MDR TB is made through rapid molecular testing (TCM) and drug sensitization testing. TCM uses Xpert MTBC RIF on sputum specimens of suspected drug-resistant TB patients to detect resistance to rifampicin.

The dependent variable in this study is time to event, with the observed event being unfavorable treatment outcome (UTO). Patients were considered to have unfavorable treatment outcome during the 11-month follow-up period since the initiation of MDR TB treatment, the final treatment outcome was death from any cause, treatment failure, and treatment dropout. The time of event occurrence was expressed in days. Meanwhile, patients were categorized as censored if the end result of MDR-TB treatment in the 11-month follow-up period was declared cured and complete treatment. The final result of cured treatment was determined by the results of bacteriological examination with BTA culture/sputum that at least two consecutive cultures taken at different times with a minimum distance of 7 days had negative results. Complete treatment is a patient who has completed treatment but does not meet the definition of cured. Treatment failure is a patient with a positive culture result at the 4th month of treatment, no clinical improvement, and evidence of additional drug resistance

to drugs in the combination. Discontinued treatment is a patient who stopped treatment for at least 2 consecutive months.

The independent variables in the study were age, gender, treatment history, treatment delays, HIV status, and comorbid DM. Data collection on the dependent and independent variables was done by looking at the data from the manual TB recording form from the available health facilities in the SITB data. Previous treatment history of MDR TB patients was categorized as yes if the patient had undergone previous TB treatment and no if they had not. Treatment delay was measured based on the time interval between the date of confirmation of MDR TB diagnosis and the date of treatment initiation, categorized as yes (>14 days) and no (≤ 14 days). HIV status was assessed by HIV rapid test and DM comorbidity was assessed by blood sugar rapid test. The data obtained were then processed and analyzed using STATA version 15 statistical software. Data analysis was performed using survival analysis. Descriptively, variable data were presented with the overall survival curve of MDR-TB patients, while categorical research subject characteristics were presented with frequency tables. Bivariate analysis was performed using Cox regression to assess the risk of death based on the categories of each independent variable, using hazard ratio (HR) estimates (95% CI) and the Wald test. Multivariate analysis was performed using Cox regression models to estimate the risk of treatment failure in MDR-TB patients during the treatment period. Before constructing the Cox regression model, the proportional hazard (PH) assumption was tested, if the PH assumption was met, the standard Cox regression model was used.

RESULT

This study analyzed data from MDR-TB patients who started treatment using a short-course regimen at the provincial TB treatment referral hospital in Jakarta. A total of 170 patients were recorded in the Tuberculosis Information System (SITB) between January 1, 2020, and December 31, 2022. After selection, based on inclusion criteria, four patients were excluded from the analysis because they were under 15 years of age and lacked treatment outcome data. Thus, a total of 166 patients met the inclusion criteria and were included in the analysis (Figure 1). Demographic and clinical characteristics of MDR-TB patients during the study period are presented in Table 1. Most patients were aged ≥ 45 years (50.6%), male (57.8%), had no prior history of TB treatment (60.8%), initiated treatment within ≤ 14 days of diagnosis (63.9%), were HIV-negative (84.9%), and did not have comorbid diabetes mellitus (70.4%).

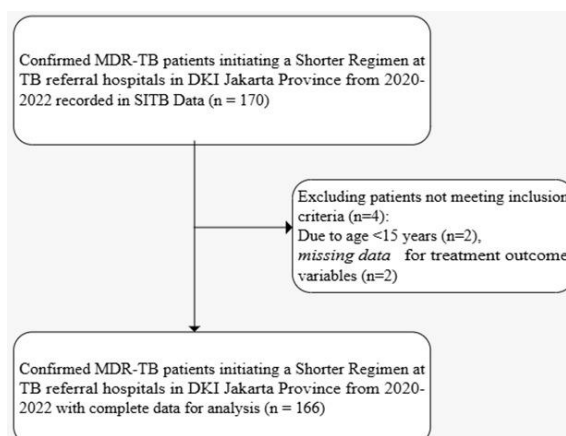


Figure 1. Research Sample Selection Flowchart

The distribution of total 166 patients, 43.4% is unfavorable treatment outcome (UTO). This category includes treatment failure (22.9%), lost to follow up (12.0%), and death (8.4%). Conversely, 56.6% of patients favorable treatment outcome (FTO), consisting of cured (50.6%) and completed treatment (6.0%) (Table 2).

Table 1.
Distribution of Characteristics of MDR-TB Patients in Short-Term Regimen

Variable	f	%
Treatment Outcome		
Unfavorable treatment outcome (UTO)	72	43.4
Favorable treatment outcome (FTO)	94	56.6
Age		
≥ 45 years	84	50.6
15-44 Years	82	49.4
Gender		
Male	96	57.8
Female	70	42.2
History of TB Treatment		
Yes	65	39.2
No	101	60.8
Treatment Delay		
> 14 days	60	36.1
≤ 14 days	106	63.9
HIV infection		
Yes	25	15.1
No	141	84.9
Diabetes Melitus (DM)		
Yes	49	29.6
No	117	70.4

Table 2.
Treatment Outcomes for MDR-TB Patients in Short-Term Regimen

Treatmen Outcome	f	%
Unfavorable treatment outcome (UTO)		43.4
Treatment failure	38	22.9
Lost to follow up	20	12.0
Death	14	8.4
Favorable treatment outcome (FTO)		56.6
Cured	84	50.6
Complete	10	6.0

The Kaplan-Meier survival curve (Figure 2) shows that the cumulative probability of patients remaining free from UTO decreases gradually during the treatment period and reaches a stable point at around 38% after day 400, 50% of patients UTO within less than 367 days of starting treatment. This indicates that approximately 62% of patients UTO during the follow-up period.

The results of the bivariate analysis of factors suspected to be associated with UTO are presented in Table 3. It was found that age, HIV status, and diabetes mellitus comorbidity had a potential association with the risk of UTO (p-value < 0.25), so all three were included in the multivariate model. Meanwhile, the variables of gender, history of TB treatment, and treatment delay did not show a statistically significant association (p-value > 0.05).

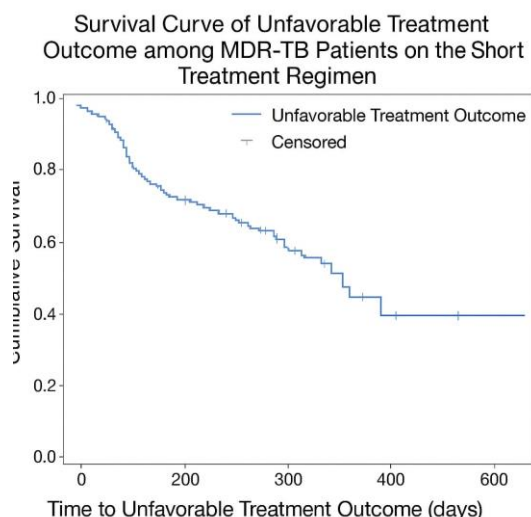


Figure 2. Survival Curve for UTO in MDR-TB Patients in Short-Term Regimen

Tabel 3.

Predictive Factors for UTO in MDR-TB Patients in Short-Term Regimen

Variable	Outcome		Assumption PH**	p-value	Crude HR (95% CI)
	UTO (n=72)	FTO (n=94)			
Age					
≥ 45 years	41 (48.8)	43 (51.2)	0.832	0.124*	1.54 (0.90 – 2.31)
15-44 Years	31 (37.8)	51 (62.2)			Ref
Gender					
Male	42 (43.8)	54 (56.2)	0.885	0.933	0.98 (0.61 – 1.57)
Female	30 (42.9)	40 (57.1)			Ref
History of TB Treatment					
Yes	31 (53.5)	34 (52.3)	0.232	0.421	1.21 (0.76 – 1.93)
No	41 (40.6)	60 (59.4)			Ref
Treatment Delay					
> 14 days	24 (40.0)	36 (60.0)	0.785	0.456	0.83 (0.51 – 1.36)
≤ 14 days	48 (45.3)	58 (54.7)			Ref
HIV infection					
Yes	21 (84.0)	4 (16.0)	0.903	<0.001*	3.30 (1.98 – 5.50)
No	51 (36.2)	90 (63.8)			Ref
Diabetes Melitus (DM)					
Yes	30 (61.2)	19 (38.8)	0.486	0.002*	2.16 (1.34 – 3.48)
No	42 (35.9)	75 (64.1)			Ref

*p-value significant enough that the variable is included in the multivariate analysis

**Assumption PH (*Proportional Hazard*) evaluated with statistical tests *Goodness of Fit* (GOF)

Before performing multivariate modeling with Cox regression, proportional hazards (PH) assumptions were tested using two approaches: visualization of log-log survival curves and evaluation of goodness-of-fit statistics. The log-log curve showed parallel patterns across variable categories, and the goodness-of-fit test results listed in Table 3 indicated that all variables did not violate the PH assumption (p-value > 0.05). Therefore, all variables met the PH assumption. The final multivariate Cox regression model (Table 4) identified HIV status and DM comorbidity as significant predictors of UTO. Patients with HIV-positive status had nearly three times the risk of UTO compared to HIV-negative patients (aHR = 2.98; 95% CI: 1.77–4.99). Additionally, patients with comorbid DM had nearly twice the risk of UTO compared to patients without DM (aHR = 1.92; 95% CI: 1.19–3.11).

Tabel 4.
Final Model of Multivariate Analysis of Predictive Factors for UTO in MDR-TB Patients in Short-Term Regimen

Variable	Koefisien	P-value	aHR	95% CI
HIV infection				
Yes	1.09	<0.001	2.98	1.77 – 4.99
No	Ref			
Diabetes Melitus (DM)				
Yes	0.65	0.008	1.92	1.19 – 3.11
No	Ref			

DISCUSSION

The results of this study show that 43.4% of MDR-TB patients is unfavorable treatment outcome (UTO). This figure is quite high compared to the MDR-TB treatment success target set by the WHO, which is above 75% (World Health Organization, 2022a). The high proportion of UTO poses a serious challenge, particularly in densely populated urban areas like Jakarta, given the complexity of management and adherence required in MDR-TB treatment. Survival analysis using the Kaplan-Meier method shows the pattern of time to UTO. The estimated median time to UTO is 367 days, indicating that most patients are able to get through the initial phase of treatment with this short-term regimen. The survival curve also shows that the risk of UTO increases gradually over time, with approximately 62% of patients is UTO during the observation period. This finding is important because it provides insight into when the risk of UTO is highest, thereby assisting healthcare professionals and policymakers in developing more timely monitoring and intervention strategies. This study found HIV-positive status and comorbid diabetes mellitus (DM) to be significant predictors of UTO in MDR-TB. Patients with HIV-positive status had an almost three times higher risk of UTO (aHR = 2.98; 95% CI: 1.77–4.99). These findings are consistent with global literature that widely recognizes HIV as a major risk factor for poor treatment outcomes in MDR-TB. A study in Indonesia conducted by Laili et al., (2024) found that TB-HIV co-infection was significantly associated with treatment failure in TB RO (p value: <0.001 aOR = 2.3, 95% CI: 1.9–6.2). Research by Riele et al., (2019) found that TB-resistant patients with HIV-positive status were 1.33 times (95% CI, 0.50–3.50) more likely to UTO. Studies have consistently shown that DR-TB patients with HIV experience unfavorable treatment outcomes such as failure, death and higher LTFU compared to patients with MDR-TB without HIV (Engoru et al., 2024; Koroma et al., 2024; Wagnew et al., 2024b).

The interaction between HIV and MDR-TB complicates the clinical management of patients with DR-TB, as the presence of HIV can lead to more severe manifestations of TB and increase drug interactions that can affect treatment success (Navasardyan et al., 2024). TB-HIV coinfection exacerbates immunosuppression, leading to suboptimal absorption of antituberculosis drugs, interactions between antiretroviral (ARV) drugs and TB drugs, and an increased risk of opportunistic infections (OIs) or immune reconstitution inflammatory syndrome (IRIS), which can complicate treatment management. Therefore, comprehensive HIV screening and integrated co-infection management are crucial in MDR-TB programs. In addition, patients with comorbid diabetes mellitus also showed an almost twofold higher risk of treatment failure compared to patients without DM (aHR = 1.92; 95% CI: 1.19–3.11). These findings align with those of Perez-Navarro et al., (2017), who reported that patients with drug-resistant tuberculosis who also have diabetes mellitus are 2.04 (1.07–3.8) times more likely to UTO. Studies have consistently shown that DM is associated with increased complications and poorer treatment response in DR-TB patients. Study in Abu Dhabi DM prevalence 46.4% of DR-TB patients had diabetes, which was significantly associated with poor treatment outcomes (Pasha & Alakkad, 2024).. Comorbidities including DM were

identified as a major predictor of unfavorable outcomes, with OR=7.555 for DR-TB patients (Babalik et al., 2024).

The mechanisms underlying this association are complex, including immune dysregulation in DM patients that reduces the response to *M. tuberculosis* infection, impaired pharmacokinetics of antituberculosis drugs, and higher risks of complications and drug side effects. The increasing prevalence of DM globally poses a public health challenge as it not only increases the risk of contracting TB but also complicates TB treatment outcomes, including DR-TB (Fu et al., 2021). Patients with DR-TB are at higher risk of treatment side effects, such as elevated serum creatinine levels, hearing loss, and delayed sputum culture conversion (Soedarsono et al., 2021). Given the increasing prevalence of DM, strengthening DM screening in MDR-TB patients and strict glycemic management are crucial for improving treatment success. Although bivariate analysis showed a potential relationship, variables such as age, gender, history of TB treatment, and treatment delay were not proven to be significant predictors in the final multivariate model of this study. This may be due to various factors such as limited sample size, specific characteristics of the study population in DKI Jakarta, or the presence of other confounding variables that were not measured. These findings sometimes differ from other studies that may find these factors to be significant.

This study has limitations, including a retrospective design with secondary data from SITB, so that researchers cannot confirm the validity of the measurement results and data entry. The varying follow-up duration among patients may affect the survival analysis results. This study focuses on a single province, limiting the generalizability of the findings to a broader population. Additionally, many other factors were not included in this study for evaluation, such as nutritional status, resistance patterns, pulmonary cavities, and patient compliance levels. Further research is also needed to investigate the side effects of short-term regimen on treatment outcomes.

CONCLUSION

This study shows that short-term regimens for the treatment of MDR-TB in DKI Jakarta Province still face major challenges, with a high proportion of unfavorable treatment outcome (UTO). The probability of survival without failure decreases significantly during the treatment period. HIV-positive status and diabetes mellitus comorbidity significantly increase the risk of UTO, so these two factors require special attention in intervention planning and strengthening of the healthcare system. Efforts to improve the success of MDR-TB treatment must include optimal screening for comorbidities, integrated management, and intensive monitoring of high-risk patients.

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