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RESEARCH ARTICLE

Adverse effects of short-term regimens in multidrug-resistant tuberculosis patients with treatment failure in Central Java, Indonesia

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ABSTRACT

Recent evidence shows high rates of treatment failure among multidrug-resistant tuberculosis (MDR-TB) patients on short-course regimens. This clinic-based case–control study used Tuberculosis Information System (SITB) data from Central Java, Indonesia (2021–2023) to examine associations between employment status, HIV status, baseline sputum examination, and body mass index (BMI) with specific categories of treatment failure (treatment failure, diagnostic change, regimen modification, loss to follow-up, and death). Overall treatment failure was 70.59%, including 15.3% deaths. Employment status was significantly associated with failure category (p=0.022), with unemployed patients disproportionately experiencing loss to follow-up (82.5%) and death (59.6%). HIV-reactive patients were more likely to undergo regimen modification (p=0.009; 1.8%). Baseline sputum results showed the strongest association (p<0.001): negative sputum was linked to diagnostic change (49.1%) and unknown sputum status to loss to follow-up (66.7%). Low BMI (<18.5 kg/m2) was also associated with failure category (p=0.037), particularly loss to follow-up (75.4%) and death (33.3%). These findings implicate socioeconomic vulnerability, HIV co-infection, absent or negative baseline sputum results, and undernutrition as important determinants of distinct short-course MDR-TB treatment failures and support integrated, patient-centred interventions to improve outcomes.

1. Introduction

Tuberculosis (TB), caused by *Mycobacterium tuberculosis*, is a contagious infectious disease that primarily affects the lungs and remains a major public health problem globally and in Indonesia. Untreated or poorly managed TB can cause permanent lung damage, ongoing transmission, and death. According to the Global TB Report 2024, an estimated 10.8 million people worldwide were infected with tuberculosis (Chen *et al.,* 2025). Indonesia has the second-highest TB burden after India; the Global TB Report 2023 estimated 1,060,000 new TB cases and 134,000 deaths annually in Indonesia (World Health Organisation, 2025).

The World Health Organisation (WHO) recommends short-course regimens (STRs, 9–12 months) as an alternative to longer regimens (LTRs)

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for multidrug-resistant TB (MDR-TB), reporting comparable or improved efficacy (Jain, 2021). Comparative studies support the effectiveness of STRs: a Pakistani study reported higher success with STRs (86.31%) than with LTRs (79.51%) and lower mortality in the STR group (4.21% vs 9.63%) (Ali *et al.,* 2024). However, clinic-based data from Malang, Indonesia, showed poor outcomes for STRs at Dr Saiful Anwar Malang Hospital, with an overall MDR-TB treatment-failure prevalence of 70.59%—including 30.6% loss to follow-up, 2.4% treatment failure, 15.3% deaths, and 22.3% switching to individualised regimens (Prasetya *et al.,* 2022).

Determinants of MDR-TB treatment outcomes reported in the literature include older age (≥48 years), male sex, homelessness, unemployment, and low education (Prasetya *et al.,* 2022; Zhdanova *et al.,* 2021). Microbiological factors such as pre-XDR-TB and other drug resistances increase failure risk (Trébucq *et al.,* 2019; WHO, 2024), while comorbidities, including HIV and diabetes, are associated with poorer outcomes. Higher dropout rates have been linked to less effective drugs and greater adverse effects (Mahardani *et al.,* 2022; Prasetya *et al.,* 2022). Health-system weaknesses—delayed treatment initiation, limited drug-susceptibility testing (DST) coverage, and slow sputum conversion—also reduce treatment success and contribute to non-adherence (Han *et al.,* 2021; Lolong *et al.,* 2023; Prasetya *et al.,* 2022).

Given these gaps, identifying distinct categories of STR-related treatment failure (treatment failure, diagnostic change, regimen modification, loss to follow-up, and death) and their determinants in clinic settings is critical to developing targeted, patient-centred interventions for MDR-TB patients.

2. Materials and Methods

2.1. Study design and setting

A nested case–control study was conducted at all Integrated Management of Drug-Resistant Tuberculosis (*Manajemen Terpadu Tuberkulosis Resisten Obat*/MTPT RO) hospitals in Central Java. We extracted data from the Tuberculosis Information System (SITB — Sistem Informasi Tuberkulosis) for patients registered between January 2021 and December 2023.

2.2. Sampling and study population:

Total sampling was applied. Of 509 registered patients, 412 had recorded treatment outcomes; 214 patients meeting the inclusion criteria (complete data for the 12 study variables) were classified as cases of treatment failure and included in the analysis.

2.3. Outcome definitions

Treatment-failure outcomes were categorized into five mutually exclusive groups: (1) treatment failure due to lack of clinical or laboratory improvement; (2) diagnostic change when a subsequent diagnosis other than TB was established; (3) regimen modification to a long-term regimen when STR proved ineffective; (4) loss to follow-up (LTFU), defined as discontinuation of treatment before completion; and (5) death during treatment from TB or other causes.

2.4. Variables and operational definitions

Explanatory variables included:

1. Drug side effects: recorded adverse events during treatment, dichotomised as present or absent.
2. Treatment initiation interval: time from initial diagnosis to treatment commencement, categorised as ≤7 days or >7 days.
3. Body mass index (BMI): categorised as underweight (<18.5 kg/m²), normal (18.5–25.0 kg/m²), and overweight/obese (>25 kg/m²).
4. BPJS insurance ownership: enrollment in BPJS health insurance during TB treatment, categorised as insured or uninsured.

2.5. Ethics

The study protocol was approved by the Ethics Committee of Universitas Jenderal Soedirman, Purwokerto, Indonesia, with approval No. EC: 1481/EC/KEPK/VI/2024.

2.6. Statistical analysis

Descriptive statistics are presented as frequencies and percentages for categorical variables. Associations between ordinal variables were assessed using the Gamma correlation test, and comparisons across more than two independent groups were performed with the Kruskal–Wallis's test. Statistical significance was set at $p < 0.005$.

3. Results

Table 1 summarizes characteristics of the 214 patients with recorded treatment-failure outcomes. Unsuccessful outcomes were distributed as follows: lost to follow-up 60 (28.0%), switched to long-term regimen 51 (23.8%), diagnostic change 42 (19.6%), death 38 (17.8%), and treatment failure 23 (10.7%). Most patients experienced drug side effects 157 (73.4%). The cohort was predominantly male (128, 59.8%) and largely unemployed (156, 72.9%). New TB cases accounted for 111 (51.9%) and retreatment cases 103 (48.1%).

Table 1. Characteristics of research respondents (n = 214)

Variable	Category	Frequency	Percent
Unsuccessful treatment outcome	Failure	23	10.7
	Failure due to Change in Diagnosis	42	19.6
	Switched to Long-Term Regimen	51	23.8
	Lost to Follow-Up	60	28
	Death	38	17.8
Drug side effects	No Side Effects	57	26.6
	With Side Effects	157	73.4
Sex	Male	128	59.8
	Female	86	40.2
Employment status	Employed	58	27.1
	Unemployed	156	72.9
History of previous tb treatment	New Case	111	51.9
	Retreatment	103	48.1
Diabetes mellitus (DM) status	Non-DM	165	77.1
	DM	49	22.9
Hiv status	Non-Reactive	136	63.6
	Reactive	2	0.9
	Unknown	76	35.5
Initial sputum examination	Negative	87	40.7
	Positive	48	22.4
	Unknown	79	36.9
Treatment initiation interval	< 7 days	32	15
	≥ 7 days	182	85
Body mass index (bmi)	BMI 17<18.5 kg/m²	143	66.8
	BMI 18.5–25.0 kg/m²	47	22
	BMI >25–27 kg/m²	24	11.2
BPJS insurance status	With BPJS	17	7.9
	Without BPJS	197	92.1
Age	Mean±SD	44.62±15.636	

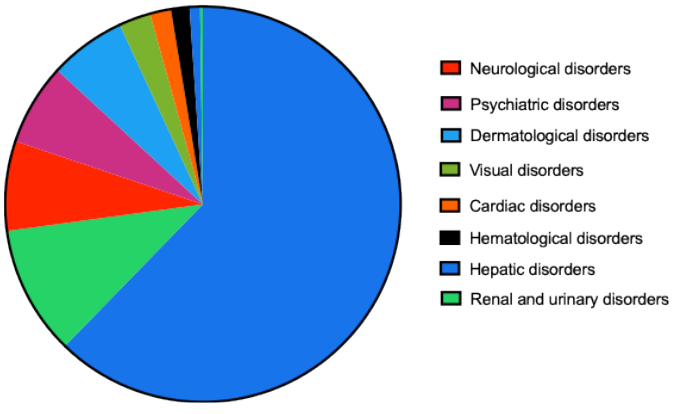


Figure 1. Types of adverse drug reactions reported among MDR-TB patients on short-course regimens (n = 464 reported events)

Diabetes mellitus was present in 49 (22.9%), while 165 (77.1%) were non-DM. HIV status was non-reactive in 136 (63.6%), reactive in 2 (0.9%), and unknown in 76 (35.5%). Initial sputum results were negative in 87 (40.7%), positive in 48 (22.4%), and unknown in 79 (36.9%). Treatment was initiated ≥7 days after diagnosis in 182 patients (85.0%) versus ≤7 days in 32 (15.0%). Nutritional status showed 143 (66.8%) underweight (BMI <18.5 kg/m²), 47 (22.0%) normal (18.5–25.0 kg/m²), and 24 (11.2%) overweight/obese (>25 kg/m²). Only 17 patients (7.9%) had BPJS insurance. Mean age was 44.62 ± 15.64 years.

Using Gamma correlation and Kruskal–Wallis tests, several factors were significantly associated with categories of unsuccessful TB treatment outcomes (Table 2). Employment status was associated with outcome category (p = 0.022); unemployed patients accounted for most of the loss to follow-up (82.5%)

Table 2. Distribution of treatment-failure categories among MDR-TB patients on short-course regimens by patient characteristics (n = 214)

Variable	Treatment Category Unsuccessful										r	r^2	*p*
	Failed		Change in diagnosis		Regimen change		Dropout		Died				
	n	%	n	%	n	%	n	%	n	%			
Drug Side Effects													
• No Side Effects	6	10.5	14	24.6	7	12.3	18	31.6	12	21.1	-0.053	0.3	0.644
• With Side Effects	17	29.8	28	49.1	44	77.2	42	73.7	26	45.6			
Sex													
• Male	14	24.6	25	43.9	33	57.9	31	54.4	25	43.9	0.011	0	0.912
• Female	9	15.8	17	29.8	18	31.6	29	50.9	13	22.8			
Employment Status													
• Employed	5	8.8	13	22.8	23	40.4	13	22.8	4	7	0.227	5.2	0.022
• Unemployed	18	31.6	29	50.9	28	49.1	47	82.5	34	59.6			
History of Previous TB Treatment													
• New Case	11	19.3	21	36.8	30	52.6	29	50.9	20	35.1	-0.005	0	0.959
• Retreatment	12	21.1	21	36.8	21	36.8	31	54.4	18	31.6			
Diabetes Mellitus (DM) Status													
• Non-DM	17	29.8	31	54.4	40	70.2	45	78.9	32	56.1	-0.106	1.1	0.358
• DM	6	10.5	11	19.3	11	19.3	15	26.3	6	10.5			
HIV Status													
• Non-Reactive	17	29.8	31	54.4	34	59.6	35	61.4	19	33.3	0.256	6.6	0.009
• Reactive	0	0	0	0	1	1.8	0	0	1	1.8			
• Unknown	6	10.5	11	19.3	16	28.1	25	43.9	18	31.6			
Initial Sputum Examination													
• Negative	8	14	28	49.1	26	45.6	12	21.1	13	22.8	0.328	10.8	0.000
• Positive	8	14	9	15.8	14	24.6	10	17.5	7	12.3			
• Unknown	7	12.3	5	8.8	11	19.3	38	66.7	18	31.6			
Treatment Initiation Interval													
• < 7 days	6	10.5	5	8.8	11	19.3	3	5.3	7	12.3	0.143	2	0.317
• ≥ 7 days	17	29.8	37	64.9	40	70.2	57	100	31	54.4			
Body Mass Index (BMI)													
• BMI 17<18.5 kg/m²	19	33.3	28	49.1	34	59.6	43	75.4	19	33.3	0.195	3.8	0.037
• BMI 18.5–25.0 kg/m²	3	5.3	11	19.3	11	19.3	10	17.5	12	21.1			
• BMI >25–27 kg/m²	1	1.8	3	5.3	6	10.5	7	12.3	7	12.3			
BPJS Status													
• With BPJS	1	1.8	2	3.5	6	10.5	6	10.5	2	3.5	-0.069	0.5	0.661
• Without BPJS	22	38.6	40	70.2	45	78.9	54	94.7	36	63.2			
• Age (mean ± SD)													**0.209**

**p.v< 0.005 ; Gamma correlation test #Kruskal-Wallis test

and deaths (59.6%). HIV status was also associated with outcome category (p = 0.009), with HIV-reactive patients disproportionately represented in the regimen-change category. Initial sputum examination showed the strongest association with outcome (p < 0.001): patients with negative initial sputum results were more likely to experience diagnostic change (49.1%) and regimen change (45.6%), whereas those with unknown sputum results were more likely to be lost to follow-up (66.7%). The "unknown" sputum category reflects missing or unrecorded results and may introduce bias in these associations. Low BMI (<18.5 kg/m²) was significantly associated with outcome category (p = 0.037), with underweight patients showing higher rates of adverse outcomes compared with other BMI groups. No significant associations

with treatment-failure category were observed for drug side effects, sex, history of previous TB treatment, diabetes mellitus status, treatment initiation interval, or BPJS insurance ownership. These findings suggest that socioeconomic vulnerability (unemployment), HIV co-infection, baseline sputum status (including missing data), and undernutrition are key correlates of distinct unsuccessful outcomes in this cohort.

Figure 1 shows that adverse drug reactions among patients with unsuccessful outcomes (total reported events n = 464) were dominated by gastrointestinal disorders (289 events, 62%), followed by musculoskeletal disorders (49 events, 11%) and neurological disorders (34 events, 7%). Psychiatric (31 events, 7%) and dermatological disorders (29 events, 6%) were also notable. Less frequent events included visual disorders (12 events, 3%), cardiac disorders (8 events, 2%), and haematological disorders (7 events, 2%). Hepatic disorders (4 events, 1%) and renal/urinary disorders (1 event, <1%) were rare. These figures represent the distribution of reported events, not the proportion of patients affected.

4. Disscussion

The main findings indicate that employment status, HIV status, baseline sputum results, and BMI were significantly associated with categories of unsuccessful MDR-TB treatment outcomes. Higher proportions of loss to follow-up and death occurred among patients who were unemployed, HIV-reactive, had negative or unknown baseline sputum results, or were underweight. Employment status was notably associated with loss to follow-up and death: 82.5% of patients classified as lost to follow-up, and 59.6% of those who died were unemployed; these figures describe the distribution of employment within outcome categories rather than the absolute risk among all unemployed patients.

Observed proportions of treatment dropout and mortality are broadly consistent with global MDR-TB patterns. WHO reports indicate improvements in treatment success (56% in 2016 → ~59% in 2018 → ~68% by 2023), yet loss to follow-up (6–16%) and mortality (9–23%) remain substantial contributors to unsuccessful outcomes (World Health Organisation, 2025). Similar patterns have been reported in high-burden settings (Achalu *et al.,* 2024; Belachew *et al.,* 2022). Between-study variation likely reflects differences in regimen composition, monitoring systems, and patient factors such as BMI, HIV co-infection, prior treatment history, and adherence (Lolong *et al.,* 2023).

Socioeconomic vulnerability plausibly mediates the association between unemployment and poor outcomes. Economic barriers reduce access to care (transport, clinic attendance), impair nutrition, and increase psychosocial burden, all of which may undermine adherence (Lolong *et al.,* 2023; Abd Rani *et al.,* 2024; Diniawati & Wibowo, 2018). This explanation aligns with Social Determinants of Health frameworks linking poverty and limited health-service access to worse disease trajectories.

HIV co-infection was associated with regimen modification in this cohort. Drug–drug interactions between antiretroviral therapy and MDR-TB regimens, and the complexity of polypharmacy, increase the likelihood of adverse effects and may necessitate regimen changes; high rates of potential drug–drug interactions (pDDIs) and associated adverse events have been reported among TB/HIV patients (Ch, 2022; de Resende *et al.,* 2021). These factors can contribute to treatment disruption and poorer outcomes.

Baseline sputum status was strongly associated with outcome categories. Patients with unknown sputum results more often experienced loss to follow-up (66.7%), while those with negative sputum results more frequently underwent diagnostic change (49.1%). Missing or negative baseline microbiology complicates diagnostic certainty and treatment decisions, and may undermine patient confidence in care, increasing the risk of discontinuation (Alene *et al.,* 2017).

Low BMI was significantly associated with dropout and mortality: underweight patients (BMI <18.5 kg/m²) had higher proportions of loss to follow-up (75.4%) and death (33.3%). Malnutrition impairs immune response to Mycobacterium tuberculosis and increases susceptibility to adverse drug reactions and treatment complications, reducing the likelihood of successful completion (Bhargava *et al.,* 2014; Niki *et al.,* 2020; Wagnew *et al.,* 2024; Wulandari *et al.,* 2024).

Adverse reaction reporting in this cohort should be interpreted in light of regimen composition, monitoring intensity, and reporting practices, which influence event frequency and detection (Kushemererwa *et al.,* 2023). The results support a Continuum of Care (CoC) approach integrating MDR-TB management with HIV services, socioeconomic support, diagnostic capacity strengthening, and nutritional interventions to reduce regimen changes, dropout, and mortality (Jakubowiak *et al.,* 2007). Enhancing adherence support (DOTS, digital reminders, telemedicine) and active monitoring for pDDIs in TB/HIV co-management may also reduce adverse outcomes.

Limitations of this facility-based study include potential selection bias and limited generalizability beyond Central Java. Use of routine SITB data exposes the analysis to information bias from missing or misclassified records (notably unknown HIV and

sputum status). The observational design and potential unmeasured confounding limit causal inference. Rare outcomes and infrequent exposures may have insufficient power for detection. Finally, event-level adverse-reaction data may overrepresent patients with multiple events.

Future research should examine prospective studies with comprehensive clinical, microbiological (including resistance profiles), adherence, and socioeconomic data. Multivariable regression, propensity-score methods, and multiple imputation for missing data would strengthen causal inference and clarify pathways linking socioeconomic status, nutrition, HIV, diagnostic gaps, and specific failure categories.

5. Conclusions

Employment status, HIV status, baseline sputum results, and low BMI were significantly associated with categories of unsuccessful MDR-TB treatment outcomes in Central Java. Programmatic actions that may reduce loss to follow-up, regimen changes, and mortality include targeted socioeconomic support for unemployed patients (e.g., transport or nutrition vouchers), strengthened TB–HIV service integration with routine HIV testing and ART–TB interaction review, wider access to rapid molecular diagnostics (e.g., Xpert MTB/RIF) to reduce diagnostic uncertainty, and nutritional support for underweight patients. Findings should be interpreted with caution due to reliance on secondary SITB data (potential missing or misclassified records) and the facility-based sample from Central Java, which may limit generalizability. Prospective studies and multivariable or intervention-based designs are recommended to confirm these associations and inform scale-up of effective interventions.

Conflict of interest

The authors declare no conflicts of interest.

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