



Research Article

Adverse Drug Reactions Increase the Risk of Drug-Resistant Tuberculosis

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ABSTRACT

Drug-resistant tuberculosis is diagnosed in Indonesia every year, and 48% of cases begin second-line TBC treatment. Cases of resistance result in high rates of TBC medication failure, increasing morbidity and death. The purpose of this study is to identify the variables that contribute to the occurrence of drug-resistant tuberculosis at the Respira Lung Hospital in Yogyakarta. The study is a quantitative analysis using a retrospective cohort design. This research included 250 TBC patients from the Respira Lung Hospital Yogyakarta between 2021 and 2022. The sampling method employed was simple random sampling. Data was collected utilizing medical records. The chi-squared and logistic regression tests were used to analyze the data. The study found that age ($p=0.033$; $RR=3.220$), drug side effect status ($p=0.001$; $RR=6.457$), gender ($p=0.098$; $RR=2.4$), medication adherence ($p=0.509$; $RR=1.457$), previous medication history ($p=1.00$; $RR=0.940$), and comorbid diseases ($p=0.520$; $RR=1.416$) were all associated with the incidence of drug-resistant tuberculosis. The most important factor influencing the occurrence of treatment-resistant tuberculosis is the variability of treatment side effects.

Keywords: Risk factors, drug-resistant tuberculosis; drug side effects

INTRODUCTION

Tuberculosis is still a frequent infectious illness in Indonesia, caused by Mycobacterium tuberculosis, often known as acid-fast bacteria, or BTA. This bacterium reproduces slowly and is sensitive to heat and sunshine (Wahyuni, 2020). Globally, tuberculosis is a significant public health issue. According to World Health Organization (WHO) figures from 2019, there were an estimated 9.96 million tuberculosis cases globally. Global TBC incidences are expected to grow by 2020, with up to 10 million individuals suffering from the disease globally. In 2021, there will be a 9.87 million drop in TBC cases (World Health Organization, 2021). Tuberculosis in Indonesia rose in 2021, with 443,235 cases discovered, up from 393,323 in 2020 (Kemenkes RI, 2021).

The annual increase in tuberculosis cases does not rule out the possibility that it is caused by a variety of factors, including patient noncompliance with medication, lack of treatment knowledge, lack of drug diagnostic services, lack of family support to motivate patients, history of previous



tuberculosis treatment, transportation, and unwanted drug side effects. Avoidable, with high rates of treatment or therapy failure, as well as mortality (Rumimpunu et al., 2018). The success of TBC therapy does not fulfill treatment compliance objectives; this condition may influence the appearance of new TBC and drug-resistant tuberculosis cases each year (Kemenkes RI, 2021). In Indonesia, 11,500 drug-resistant tuberculosis patients were detected and reported, with around 48% of them beginning second-line TBC therapy and a treatment success rate of 45% (Kemenkes RI, 2021).

According to early investigations, the Special Region of Yogyakarta has the greatest number of drug-resistant tuberculosis cases in Indonesia, with case results varying between 2020 and 2021. According to reporting findings from the Yogyakarta Special Region Health Service, the number of drug-resistant tuberculosis cases rose from 2020 to 2021, with 7 cases. In 2020, 39 drug-resistant tuberculosis cases were confirmed. Meanwhile, drug-resistant tuberculosis infections increased in 2021, with 46 cases confirmed. In general, three factors contribute to bacterial resistance to anti-tuberculosis drugs: treatment that does not use the appropriate combination of dose, type, number of drugs, and treatment period; service providers (health workers) who make incorrect diagnoses; and patient education. Which is insufficient (Kemenkes RI, 2020). Other health issues that might raise the risk of drug-resistant tuberculosis include patient adherence to medicine, past treatment history, drug adverse effects, HIV, diabetes mellitus, smoking, and other factors that impair the body's resistance (Pangaribuan et al., 2020).

Problems that often occur and are the main challenge in dealing with TB are non-compliance with treatment, due to the long duration of therapy (at least six months without interruption), side effects of drugs that can disrupt comfort and lack of social support that can lead to treatment failure, transmission to others, relapse, becoming drug-resistant TB and even death. During the therapy phase, patients are frequently threatened with discontinuing treatment or dropping out. This scenario will have an impact on the development of TBC immunity or resistance to anti-tuberculosis medications (Pasaribu et al., 2022). The adverse effects that patients frequently encounter during anti-tuberculosis drugs treatment are one of the elements that make this condition difficult to treat and can cause patients to become noncompliant with their medication (Afilla Christy et al., 2022). Drug side effects associated with tuberculosis therapy range from moderate to severe. If these adverse effects are not recognized and handled promptly by health personnel, patients may cease taking medicine on a partial or total basis (Aminah & Djuwita, 2021). Many variables can impact anti-tuberculosis drugs side effects, including the patient's age, medication dose and time of administration, nutritional state, and the existence of other comorbid illnesses such as alcoholism, diabetes mellitus, liver function disorders, kidney function disorders, and HIV co-infection (Oliviera et al., 2016).

People with a history of TBC therapy are 3.54 times more likely to acquire drug-resistant tuberculosis than those without a history of TBC treatment (Buryanti & Fibriana, 2021). Patients with TBC who have had inadequate earlier therapy are 40 times more likely to acquire anti-tuberculosis drugs resistance (Manggasa & Suharto, 2022). According to early data, Respira Lung Hospital Yogyakarta is one of the drug-resistant tuberculosis referral hospitals in Yogyakarta's Special Region. In 2020, nine instances of drug-resistant tuberculosis were confirmed. Furthermore, the number of confirmed drug-resistant tuberculosis cases in 2021 has reduced to seven. There will be more confirmed instances of drug-resistant tuberculosis patients in 2022 than in 2021, when there were 14.

MATERIAL AND METHODS

This is a quantitative study employing a cohort retrospective method. The study's independent factors included age, gender, medication adherence, treatment history, drug side effects, and comorbid disease. The operational definitions of the variables used in this study are as follows:

Table 1. Operational definitions of research variables

Variable	Operational definitions	Measuring	Scale	Category
Drug-resistant tuberculosis cases	Patients diagnosed with drug-resistant tuberculosis at the Yogyakarta Respira Pulmonary Hospital between 2021 and 2022	Medical records	Nominal	1. Yes: Patients diagnosed with drug-resistant tuberculosis based on laboratory test results 2. No: Patients not diagnosed with drug-resistant tuberculosis
Age	The patient's age at the time of TBC diagnosis is determined based on medical records	Medical records	Ordinal	1. >40 years 2. ≤ 40 years
Sex	Sex of TBC patients recorded in the medical records of the Yogyakarta Respira Lung Hospital	Medical records	Nominal	1. Male 2. Female
Medication adherence	Patient adherence to TBC treatment is based on medication adherence and follow-up from initial diagnosis to the end of treatment at the Yogyakarta Respira Pulmonary Hospital	Medical records	Nominal	1. Non-adherent: Patients who do not regularly take their medication every day during TBC treatment. 2. Adherent: Patients who regularly take their medication every day during TBC treatment without missing a single dose
Treatment History	Whether or not the patient has received previous TBC or anti-tuberculosis drugs treatment at the Respira Lung Hospital	Medical records	Nominal	1. Yes: Patients with a history of previous TB treatment 2. No: Patients with no previous treatment history
Drug side effects	Some responses experienced by TBC patients to anti-tuberculosis drugs include shortness of breath, nausea, itching, dizziness, loss of appetite, weakness, fever, tingling, vomiting, joint pain, abdominal pain, difficulty swallowing, difficulty defecating, and body aches, according to medical records.	Medical records	Nominal	1. Yes: The respondent experienced drug side effects 2. No: The respondent did not experience drug side effects.
Comorbid disease	One of the additional illnesses in addition to the primary illness of a TBC patient, including diabetes mellitus, HIV, cancer, hypertension, and asthma, as recorded in medical records	Medical records	Nominal	1. Yes: Respondent has comorbidities 2. No: Respondent does not have comorbidities

The study was conducted at the Respira Pulmonary Hospital Yogyakarta, utilizing secondary data from 2021 and 2022. The population of this study consisted of all TBC patients who were reported to have received treatment in 2021-2022, totalling 332 individuals. The sample size was

calculated to be 250 people using a simple random sampling approach. Respondents were obtained through a rotating savings and credit mechanism based on medical record numbers. Then, the selected respondents were checked for the completeness of their data based on the research variables. If incomplete data were found, the respondents were excluded. The acquired data were evaluated using the chi-square test, followed by logistic regression analysis to identify the factors most strongly related to the occurrence of drug-resistant tuberculosis. The Health Research Ethics Committee of the Yogyakarta Respira Lung Hospital approved this study, which has the registration number 022/KEPK/IX/2023.

RESULTS AND DISCUSSION

Respondent characteristics include age, gender, drug side effects, and comorbid diseases (Table 2). Table 2 shows that the majority of respondents were aged >40 (59.6%), male (60%), side effects of drugs for shortness of breath were 23.1%, and comorbid diabetes mellitus (DM) was 28.8%.

Table 2. Frequency Distribution of Respondents Based on TB Patient Characteristics in 2021-2022 at Respira Lung Hospital Yogyakarta.

Variable	n	%
Age		
>40 years	149	59.6
≤40 years	101	40.4
Sex		
Female	150	60.0
Male	100	40.0
Drug side effects		
Congested	99	23.1
Nauseous	45	10.5
Itchy rash	39	9.1
Dizzy	29	6.7
No appetite	28	6.5
Weak	18	4.2
Fever	15	3.5
Tingling	14	3.2
Vomit	11	2.5
Joint pain	9	2.1
Stomachache	8	1.8
Painful to swallow	5	1.1
Difficulty defecating	5	1.1
Body aches	5	1.1
None	98	22.8
Comorbid Diseases		
Diabetes mellitus	72	28.8
Hypertension	1	0.4
Asthma	15	6.0
None	162	64.8

The bivariate analysis findings attempt to identify the factors linked with the incidence of drug-resistant tuberculosis (Table 3). The chi-square test analysis revealed that age and pharmacological side effects were associated with the occurrence of drug-resistant tuberculosis, but gender, medication compliance, treatment history, and concomitant conditions were not. Multivariate analysis using a logistic regression test on the variables age, gender, and side effects of drugs with drug-resistant tuberculosis (Table 4) reveals that the factor with the greatest influence on the incidence of drug-resistant tuberculosis is the status of risky drug side effects, which is 6.036 times the occurrence of drug-resistant tuberculosis events

Table 3. Bivariate analysis results

Variable	Drug-resistant tuberculosis incidence				Total		Sig.	OR (CI 95%)
	Yes		No					
	n	%	n	%	n	%		
Age								
< 40 years	19	7.6	130	87.2	149	59.6	0.033	3.220 (1.129-9.185)
≤ 40 years	4	1.6	97	38.8	101	40.4		
Sex								
Male	18	7.2	132	52.8	150	60.0	0.098	2.4 (0.921-6.255)
Female	5	2.0	95	38.0	100	40.0		
Medication aderance								
No	8	3.2	59	23.6	67	26.8	0.509	1.457 (0.647-3.728)
Yes	15	6.0	168	67.2	183	73.2		
Treatment history								
Yes	2	0.8	20	8.0	22	8.8	1.000	0.940 (0.235-3.757)
No	21	8.4	207	82.8	228	91.2		
Drug side effects								
Yes	20	8.0	107	42.8	127	50.8	0.001	6.457 (1.968-21.179)
No	3	1.2	120	48.0	123	49.2		
Comorbid disease								
Yes	10	4.0	78	31.2	88	35.2	0.520	1.416 (0.648-3.097)
No	13	5.2	149	59.6	162	64.8		
Total	23	9.2	227	90.8	250	100.0		

Table 4. Multivariate analysis result

Variable	Sig.	Exp (B)	Confidence Interval (95%)	
			Lower	Upper
Age	0.138	0.420	0.133	1.322
Sex	0.190	2.028	0.704	5.844
Drug side effects	0.005	6.036	1.714	21.255

1. Age

According to the findings of a study done on TBC patients at Respira Lung Hospital Yogyakarta during 2021-2022, there is a link between age and the occurrence of drug-resistant tuberculosis. Individuals over 40 have a higher chance of developing Drug-Resistant Tuberculosis compared to those under 40. According to studies, this might be because as you age, your body's resistance/immunity decreases, making the disease easier to catch. This is consistent with studies that suggest that as you become older, your body's resistance decreases,

making it easier to become unwell (Lestari et al., 2022a). Age, particularly drug-resistant tuberculosis, can have an impact on treatment completion because age affects lymphocyte cell production; the fewer lymphocyte cells generated, the weaker the immune system, causing infection resistance to function more slowly (Lestari et al., 2022b). As the patient ages, the body's metabolism and organ performance decline, increasing the likelihood of recurrent therapy. The age of TBC patients can have an impact on anti-tuberculosis drugs performance since medication metabolism and body organ function becomes less efficient as people age (Annisa & Hastono, 2019). This might lead to therapy failure in elderly individuals, potentially resulting in medication resistance. Furthermore, age influences disease exposure. A person's immune system weakens with age, increasing the risk of catching illness. The loss in physical and psychological functionality associated with rising age may also be related to increasing age, limiting patients' capacity to access health services and necessitating social support to seek treatment and take medicine regularly (Anisah et al., 2021). Family support can be used to keep the patient motivated and to oversee drug administration while undergoing treatment.

2. Sex

According to the findings of a study done on TBC patients in 2021-2022 at Respira Lung Hospital Yogyakarta, there was no association between sex and the occurrence of drug-resistant tuberculosis. Furthermore, males are more likely to develop drug-resistant tuberculosis than females. According to studies, male smoking habits make them more susceptible to tuberculosis infections. Drug-resistant tuberculosis illness affects males more than females because most males smoke, making it easier to catch (Anisah et al., 2021). Aside from that, researchers believe that sex has no impact on the development of this disease; nonetheless, behaviors such as smoking make males more vulnerable. Males' lifestyles are more prone to drug-resistant tuberculosis due to greater smoking and alcohol consumption rates, disparities in activities outside the house, and more exposure to air pollution. Furthermore, male patients with drug-resistant tuberculosis are more likely to have a lack of rest and a higher workload, making it harder for them to take medicine regularly (Bawonte et al., 2021). Males who have a history of smoking or drinking are more likely to get tuberculosis, be resistant to isoniazid and streptomycin, and have higher creatinine, ALT, GGT, and total bilirubin levels. Stopping smoking and limiting alcohol usage can improve compliance with first-line TBC medication and reduce the incidence of drug-resistant tuberculosis in males (Baluku et al., 2021).

3. Medication compliance

According to the findings of a study done on TBC patients at Respira Pulmonary Hospital Yogyakarta from 2021 to 2022, there was no association between treatment adherence and the occurrence of drug-resistant tuberculosis. According to experts, based on research done utilizing patient medical data at Respira Pulmonary Hospital Yogyakarta, many patients who are compliant and non-compliant in taking medicine have the same risk of developing drug-resistant tuberculosis. Patients who take their medicine consistently have the same risk of developing recurrent tuberculosis (Marini et al., 2023). To avoid drug-resistant tuberculosis and treatment failure, medication adherence is critical during therapy. Failure of TBC patients to take treatment regularly remains an impediment to reaching a high cure rate. Bacterial resistance to anti-tuberculosis drugs will rise due to the increased medication withdrawal rate (Aristiana & Wartono, 2018). Aside from that, failing to take medicine regularly and within the time frame specified is the leading cause of treatment failure. Patients may find it challenging to continue with the treatment procedure owing to the length of time. Patients think that too

much medicine might interfere with their regular activities (Wahyuni & Cahyati, 2020). The recovery of tuberculosis patients is also dependent on their desire and readiness to follow the doctor's advice. Adhering to the guidelines for taking medicine is critical in TBC therapy because it increases the likelihood that the disease will be treated within the specified time frame and reduces the chance of drug resistance (Sitopu et al., 2022).

4. Treatment history

According to the findings of a study done on TBC patients in 2021-2022 at Respira Lung Hospital Yogyakarta, there was no association between past treatment history and the occurrence of drug-resistant tuberculosis. According to researchers, based on research conducted using patient medical records, more patients have no history of previous or recent treatment who could be infected by drug-resistant tuberculosis patients, exposing them directly to drug-resistant tuberculosis bacteria. Patients who are diagnosed with drug-resistant tuberculosis who have never undergone anti-tuberculosis drugs treatment or are new cases may have had close contact with prior drug-resistant tuberculosis patients, or the patient may have failed to submit adequate information regarding past treatment (Manggasa & Suharto, 2022). According to the researchers, patients who have not previously had treatment can only be infected through the air from splashes of phlegm from drug-resistant tuberculosis patients who cough without covering their lips. drug-resistant tuberculosis transmission can occur via phlegm splashes from drug-resistant tuberculosis patients who cough without covering their lips. Inhaling air harboring these bacteria is likely to result in a drug-resistant tuberculosis illness. This occurs as our body's tolerance against drug-resistant tuberculosis bacteria declines (Damayanti et al., 2022). Inappropriate past therapy and drug dosages can also impact the development of drug-resistant tuberculosis; TBC patients who have previously received treatment are more likely to acquire drug-resistant tuberculosis than fresh TBC patients (Manggasa & Suharto, 2022).

5. Side effects of medications

According to the findings of a study done on TBC patients in 2021-2022 at Respira Lung Hospital Yogyakarta, there is a link between medication side effect status and the occurrence of drug-resistant tuberculosis. Furthermore, those with drug side effects are more likely to develop drug-resistant tuberculosis than people without drug adverse effects. Patients with tuberculosis who encounter pharmacological adverse effects are more likely to discontinue therapy, perhaps leading to drug resistance. As a result, health centers and hospital personnel must monitor patients who have pharmacological adverse effects (Wahyuni & Cahyati, 2020). The adverse effects that patients frequently encounter during anti-tuberculosis drugs treatment are one of the elements that make this condition difficult to treat and cause patients to be noncompliant with their medication (Christy et al., 2022). Drug side effects are frequent during TBC therapy and can range from minor to severe. These adverse effects might prompt patients to miss doses of medicine or to discontinue it entirely. If these adverse effects are not disclosed and addressed promptly by a doctor (Aminah & Djuwita, 2021). Many variables can impact anti-tuberculosis drugs side effects, including the patient's age, the amount and timing of medication use, the existence of other comorbid conditions, and nutritional status, such as drunkenness, impaired liver function, impaired renal function, and HIV co-infection (Oliviera et al., 2017). Nausea, vomiting, crimson urine, stomach discomfort, tingling, itching of the skin, reduced appetite, and pre-icteric hepatitis are common side effects described by both new and relapsed TBC patients (Gumanti et al., 2020).

6. Comorbid illness

In a study conducted on TBC patients at Respira Lung Hospital Yogyakarta from 2021 to 2022, it was found that there was no association between concurrent conditions and the occurrence of drug-resistant tuberculosis. The researchers noted that based on medical records, more drug-resistant tuberculosis patients did not have comorbid diseases than those who did. Even when patients had comorbid diseases, they continued their medication to avoid treatment failure, which can lead to resistance. When TBC is combined with other disorders, it can impair the function of the body's defense or immunological cells. A weakened immune system can lead to faster growth of germs and their pathophysiological processes, resulting in mild and nonspecific symptoms such as fever, weight loss, night sweats, fatigue, pleurisy, and lymphadenitis. Relapse can occur when the immunity of TBC patients deteriorates, and concomitant conditions like diabetes can delay sputum conversion time. (Tetrapoik et al., 2020).

Various medical conditions that TBC patients may have, such as diabetes, HIV, hypertension, asthma, and cancer, can hinder treatment effectiveness and increase tuberculosis death rates. These conditions reduce the patient's ability to combat TBC germs. TBC patients with concurrent disorders are classified into infectious diseases (such as HIV) and noncommunicable diseases (such as diabetes). In order to improve treatment success and prevent drug side effects that may cause patients to be non-compliant with their medication, it's important to have knowledge about how comorbid diseases and side effects of first-line anti-tuberculosis drugs are spread among tuberculosis patients who receive treatment. Additionally, understanding how to avoid drug side effects that lead to non-adherence to medication is crucial in preventing drug resistance (Oliviera et al., 2017).

7. Factors most associated with the occurrence of drug-resistant tuberculosis.

Factors most associated with the occurrence of drug-resistant tuberculosis included age, gender, and medication side effects, all of which had p-values <0.25 , meeting the conditions for multivariate analysis. The findings of the multivariate analysis revealed that the presence of medication side effects was the most influential factor in the incidence of drug-resistant tuberculosis. During therapy, the most prevalent adverse effect reported by patients was shortness of breath, affecting up to 99 individuals (30%). Nausea was the second most frequently reported adverse effect, affecting up to 45 individuals (45%). Other adverse effects reported by patients during treatment included itching, vomiting, dizziness, lack of appetite, tingling, difficulties swallowing, difficulty defecating, joint pain, weakness, stomachache, body pains, and fever.

The adverse effects of medications during tuberculosis therapy are influenced by several factors, including long treatment durations and the use of various anti-tuberculosis drugs. It is crucial to monitor medication side effects in TBC patients, as some may experience adverse effects. These drugs can cause a range of adverse effects, from minor to severe. If symptoms are mild and can be managed with symptomatic medications, anti-tuberculosis drugs may still be administered (Kurniasih & Nurfajriani, 2021). The use of anti-tuberculosis drugs in TBC therapy can lead to negative effects that may harm various bodily organs, such as heart disease, gastrointestinal problems, dermatological diseases, hearing disorders (ototoxicity), neurological system disorders (peripheral neuropathy), nephrotoxicity, and liver function abnormalities (hepatotoxicity) (Gumanti et al., 2020). There are several methods to prevent side effects of tuberculosis drugs, including monitoring and evaluating the side effects felt by

patients so that treatment can continue. Patients are advised to consume nutritious food, exercise, and adhere to the treatment regimen regularly for successful treatment.

This study is a retrospective cohort study using secondary data, there are limitations to the study that may include information bias that may affect causality between variables, including data not being collected specifically for the study, so important information in medical records may be incomplete and inconsistent, researchers cannot control variables that have occurred due to dependence on records, the data is retrospective, making it difficult to accurately determine the time sequence between variables.

CONCLUSION AND SUGGESTION

The occurrence of side effects from tuberculosis medications is a major factor in the development of treatment-resistant TBC. The hospital closely monitors and assesses the management of tuberculosis patients who encounter issues while undergoing treatment. Special attention is given to patients with additional health conditions and those who experience side effects to ensure they adhere to the medication regimen and prevent treatment failure, which can contribute to drug resistance.

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CONFLICT OF INTEREST

There is no conflicts of interest in this research.

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