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Medication Profile and Side Effect - Severity of Anti-Tuberculosis Drugs in Pulmonary Tuberculosis Patient at Bhina Bhakti Husada Rembang Hospital

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ABSTRACT

Purpose: This study aimed to identify the treatment profile and the type and severity of anti-tuberculosis drug (OAT) side effects in pulmonary tuberculosis patients at Bhina Bhakti Husada Rembang Hospital. It was hypothesized that most patients would receive first-line OAT regimens and experience side effects predominantly of moderate severity.

Research Method: This study used a descriptive observational method with a cross-sectional design. Data were obtained retrospectively from the medical records of 106 patients with pulmonary tuberculosis receiving first-line OAT therapy at Bhina Bhakti Husada Rembang Hospital. The variables included patient characteristics, treatment patterns, types of OAT side effects, and severity of adverse drug reactions. Data were analyzed using univariate descriptive analysis.

Results and Discussion: Most patients were aged 41-60 years (43.4%), male (64.2%), had a body weight of 30-49 kg (61.3%), and underwent treatment for 1-3 months (42.5%). The most common regimen was category 1 RHZE 2 FDC (39.6%). The most frequent side effects were reddish urine (100.0%), nausea and vomiting (83.0%), and flu syndrome (70.8%). Most side effects were categorized as moderate (56.6%).

Implications: The findings emphasize the importance of routine monitoring and early management of OAT side effects, particularly during the early treatment phase. Further studies are needed to examine risk factors associated with severe adverse reactions and their impact on treatment adherence.

Keywords: pulmonary tuberculosis; anti-tuberculosis drugs; adverse drug reactions; side effects severity; treatment profile; pharmacovigilance;.

1. Introduction

Tuberculosis (TB) is still a global health challenge, including in Indonesia. This disease is an infection that can be transmitted by Mycobacterium tuberculosis, rod-shaped aerobic bacteria. TB infection generally attacks the respiratory system, especially the lungs, and can trigger symptoms such as chronic cough, fever, and weight loss. Bacteria Mycobacterium tuberculosis It tends to multiply in tissues with high oxygen concentrations, so the apical area of the lungs is often the site of infection. The diagnosis of TB can be established through a microscopic examination of Acid-Resistant Bacilli (BTA) using a specimen of a morning smear smear, or through the GeneXpert method using a morning or random sputum specimen. A person is declared to have tuberculosis if the BTA result shows positive, if the BTA

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result is negative, then the diagnosis is followed by clinical evaluation and radiological examination. Patients with thoracic photographic images consistent with tuberculosis can be categorized as cases of tuberculosis with a clinical diagnosis (Sigh) et al., 2021).

Based on the WHO report (World Health Organization), Tuberculosis is the second leading cause of death in the world among infectious diseases. The Global Tuberculosis Report (2024), states that Indonesia ranks second in the world after India in terms of the number of tuberculosis cases. Each year it is estimated that there are about 1,090,000 cases with 125,000 deaths, equivalent to an average of 14 deaths per hour (Ministry of Health of the Republic of Indonesia, 2025). In 2024, around 885,000 cases of tuberculosis will be recorded in Indonesia, with case distributions including 496,000 in males, 359,000 in females, and 135,000 cases in children aged 0-14 years (Ministry of Health of the Republic of Indonesia, 2025). At the provincial level, Central Java is among the provinces with a high proportion of TB cases. The 2023 report shows that 87,074 cases were recorded in the province, exceeding the estimated national target. Rembang Regency itself, data from BPS (Central Statistics Agency) shows that there are around 216 cases of tuberculosis according to the type of disease reported in 2023. This condition indicates that the burden of tuberculosis in Rembang is significant and relevant for research on the side effects of OAT in pulmonary tuberculosis patients (BPS, 2024).

Tuberculosis control efforts are carried out through a strategy Directly Observed Treatment Short-course (DOTS), which is a therapeutic approach with direct observation using first-line Anti-Tuberculosis Drugs (OAT). The tuberculosis therapy process is divided into two phases, namely the intensive phase for two months and the advanced phase for four months. The purpose of this phase division is to ensure successful therapy and prevent the emergence of drug resistance. The chosen therapy regimen should include drugs that are effective against Mycobacterium tuberculosis, and patients are required to adhere to the rules of medication consumption according to the guidelines until the entire series of therapy is completed (Sigh) et al., 2021). The anti-tuberculosis drug regimen includes a combination of isoniazid, rifampicin, pirazinamide, and ethambutol, which are given for a minimum of 6 months to achieve recovery. Anti-tuberculosis drugs can interact with the body as well as with other drugs so that they have the potential to cause side effects. Failure of tuberculosis therapy can be influenced by various factors, one of which is the appearance of drug side effects. Adverse Drug Reaction (ADR) is an unexpected reaction that arises during the patient's course of therapy. The appearance of these side effects is influenced by a number of factors, including the dosage and duration of drug use, the patient's age, weight, and the presence of comorbidities such as liver dysfunction, kidney disorders, or coinfections Human Immunodeficiency Virus (HIV) (Nasichah et al, 2024).

Side effects of Anti-Tuberculosis Drugs (OAT) can be classified into two types, namely mild side effects, such as nausea and skin rashes to severe side effects, such as hepatotoxicity, optic neuropathy, and kidney disorders (Oliviera) et al., 2020). Cohort studies in Indonesian hospitals show that 15–25% of pulmonary tuberculosis patients experience moderate to severe side effects, with risk factors such as old age, comorbidities (such as HIV or diabetes), and duration of treatment contributing to increased severity (Laíse, 2022). At the local level, Bhina Bhakti Husada Rembang Hospital, as a type C health facility in rural areas of Central Java, reported an increase in pulmonary tuberculosis cases by 12% in 2022 compared to the previous year, with the main challenge being delays in the diagnosis and management of OAT side effects due to limited resources (Rembang Regency Health Office, 2023). However, data on the type and severity profile of ESO (Drug Side Effects) in pulmonary tuberculosis patients at the regional hospital level are still limited. Most studies only assessed the prevalence of side

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effects or their association with specific comorbidities, without specifically describing the severity of ESO.

This study is important to describe the profile of the type and severity of OAT side effects in pulmonary tuberculosis patients, due to the lack of local data on the type and severity of OAT side effects in pulmonary tuberculosis patients in the regions, especially at Bhina Bhakti Husada Rembang Hospital as one of the regional hospitals that is a referral for TB treatment. The results of this study are expected to be used as a basis for monitoring, early detection, and management of OAT side effects in health care facilities as well as adding to the scientific literature on OAT pharmacovigilance in pulmonary tuberculosis patients in Indonesia, especially in the severity of ESO, which is still rarely studied in regional hospitals.

2. Literature Review and Hypothesis Development

2.1 Tuberculosis

Tuberculosis is a bacterial infection caused by Mycobacterium tuberculosis, which is a rod-shaped bacteria that are aerobic in nature. This infection generally affects the parenchyma tissue of the lungs (pulmonary tuberculosis), although this bacteria can spread and infect the bacteria also has the ability to spread and infect other organs. In addition to the lungs, Mycobacterium tuberculosis It can also attack a variety of other organs, known as extrapulmonary tuberculosis, including the lung membranes, lymphatic system, skeleton, and other internal organs (Ministry of Health of the Republic of Indonesia, 2020). Tuberculosis (TB) is a disease that can spread through the air (Airborne Disease) which is generally caused by Mycobacterium tuberculosis, although other species such as M. africanum, M. bovis, and M. leprae It has also been reported to act as an infectious agent. These bacteria are known as Acid Resistant Bacilli (BTA). Characteristically, Mycobacterium tuberculosis It is a gram-positive intracellular pathogenic bacterium that enters the human lungs through the aerosol route. When people with tuberculosis sneeze or cough, thousands of germ particles can be released into the air in the form of phlegm droplets. These microscopic particles are able to survive in the air, then inhale and settle in the alveoli of exposed individuals. Infections that occur in individuals with a good immune system are generally in a dormant state, known as latent tuberculosis. This condition does not cause clinical symptoms and cannot be contagious. Latent infections will develop into active TB when an individual's immune system declines (Azkia et al., 2024).

2.2 OAT (Anti-Tuberculosis Drug)

Antituberculosis drugs are a key component in the management of tuberculosis, which requires a relatively long duration of therapy ranging from six to nine months. This therapy involves the use of OATs, which are classified by line of therapy. The first-line OAT consists of isoniazid (H), rifampicin (R), pyrazanide (Z), ethambutol (E), and streptomycin (S). Based on the category, TB therapy is classified into three groups, namely category 1, category 2, and pediatric category. Category 1 is intended for new patients, either based on clinical, bacteriological findings, or cases of extrapulmonary tuberculosis, with a standard combined regimen of 2HRZE followed by 4HR (Fortune et al., 2022).

OAT preparations are formulated in the form of Fixed Dose Combinations (KDT) or single preparations. In general, TB treatment consists of two phases, namely the intensive phase (H; R; Z; E) and advanced phases (R; H). The advanced phase functions to eradicate dormant or persistent

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tuberculosis bacilli, so that it can prevent recurrence in patients. If the basil doman is not eliminated optimally, there is a risk of reactivation of the disease in the future (Ministry of Health of the Republic of Indonesia, 2020).

2.3 ESO (Drug Side Effects)

Reactions that arise during OAT pharmacological therapy are the main factors that can interfere with the effectiveness of therapy. This condition often results in a decrease in patient compliance in taking medication consistently. Most patients report discomfort due to side effects experienced during the therapy period (Reuben et al., 2023). Long-term use of a combination of several OATs has the potential to cause unwanted drug reactions with a diverse spectrum, ranging from mild to severe. Common reported manifestations include gastrointestinal disorders, allergic reactions, joint pain, neurological disorders, and liver damage. The incidence of ESO in tuberculosis patients is reported to vary significantly, ranging from 5.1% to 83.5% depending on the patient population, the type of OAT used, as well as individual risk factors (Yati et al., 2023).

The majority of tuberculosis patients are able to complete OAT therapy without a serious drug reaction. However, a minority of patients may experience reactions that are significant enough to have an impact on daily activities. Monitoring of clinical conditions during therapy is essential to ensure early detection and optimal management of drug effects (Reuben et al., 2023). One common drug reaction is peripheral neuropathy, which is characterized by numbness or a burning sensation in the upper and lower extremities. This condition is more at risk of occurring in certain groups such as pregnant women, HIV patients, individuals with malnutrition, a history of alcohol consumption, diabetes mellitus, chronic liver disease, and kidney failure. Patients with these risk factors are recommended to receive pyridoxine supplementation of 25 mg/day in conjunction with the OAT regimen, to prevent the occurrence of peripheral neuropathy (Reuben et al., 2023).

2.4 ESO Severity

Mild side effects are side effects that are minimal or mild, do not interfere with daily activities, and do not require special intervention or changes in therapy. Moderate side effects are side effects that begin to interfere with daily activities and require minimal intervention or supportive therapy, but do not require discontinuation of primary therapy. Severe side effects are side effects that significantly limit daily activities and require medical intervention or temporary discontinuation of therapy. If the drug reaction is categorized as serious, OAT therapy is immediately stopped, then the patient needs to be referred to an advanced health facility for a more comprehensive evaluation and management (Ministry of Health of the Republic of Indonesia, 2020).

3. Research Method

This study uses a quantitative method with a non-experimental observational design and uses a Cross-sectional, because it only observes a condition in the population without providing intervention (Rosnarita, 2025). This study describes the type profile and classifies the severity of the side effects of anti-tuberculosis drugs experienced by pulmonary tuberculosis patients. The population in this study included patients diagnosed with pulmonary tuberculosis, both men and women who received OAT

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therapy at Bhakti Husada Rembang Hospital. The number of populations is not listed because it uses the formula Lemma. The sample in this study was n = 96.04 plus 10% for drop out, so that the total was 105.6 rounded to 106 samples. The instruments used include patient medical record records, data collection form sheets(Setyowati) et al., 2021). Severity measurement uses the Indonesian Ministry of Health's classification (2020) which divides ESO into mild, moderate, and severe based on its impact on therapy. The data analysis used was univariate analysis.

4. Results and Discussion

4.1 Analysis Results

4.1.1 Characteristic of Sample

Based on table 1, it shows that the age of patients suffering from pulmonary tuberculosis is the most 41-60 years old with a total of 46 patients (43.4%), the age of >60 years with the number of patients 32 people (30.2%), and the age of 20-40 years with the number of patients 28 people (26.4%). Based on gender, the most patients suffering from pulmonary tuberculosis were men with 68 patients (64.2%), and women with 38 patients (35.8%). The weight distribution of patients suffering from pulmonary tuberculosis was 30-49 kg (61.3%), >50 kg (29.2%), and <30 kg (9.4%).

Table 1. Baseline Characteristic of Sample

Yes	Characteristics	Frequency (F)	Present (%)
1	Age		
	20-40 Years	28	26,4
	41-60 Years	46	43,4
	>60 Years	32	30,2
2	Gender		
	Male	68	64,2
	Women	38	35,8
3	Weight		
	<30 kg	10	9,4
	30-49 kg	65	61,3
	>50 kg	31	29,2
4	Education		
	Not in school	35	33,0
	SD	12	11,3
	Junior High School	22	30,8
	High School	36	34,0
	Bachelor	1	0,9
5	Duration of Treatment		
	<1 Month	33	31,1
	1-3 Months	45	42,5
	4-6 Months	22	20,8
	>6 Months	6	5,7

Source: *Primary data, 2026*

Based on the education level of patients with pulmonary tuberculosis, namely out of school with 35 patients (33.0%), high school with 36 patients (34.0%), junior high school with 22 patients

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(20.8%), elementary school with 12 patients (11.3%), and bachelor with 1 patient (0.9%). Based on the length of treatment, most of the patients who underwent treatment for 1-3 months (42.5%), <1 month were 33 patients (31.1%), the duration of treatment was 4-6 months as many as 22 people (20.8%), and the duration of treatment was >6 months (5.7%).

4.1.2 Treatment Pattern

Based on table 2, it is known that the treatment pattern of tuberculosis patients most uses OAT category 1 RHZE 2 FDC as many as 42 patients (39.6%). Furthermore, OAT category 1 RHZE 4 FDC was used by 31 patients (29.2%). OAT category 1 RHZE is a first-line regimen consisting of a combination of Rifampicin (R), Isoniazid (H), Pyrazanide (Z), and Etambutol (E) given in the intensive phase of treatment. The Fixed Dose Combination (FDC) form is used to increase patient adherence, reduce the risk of misuse of a single drug, and prevent the occurrence of resistance. The difference between RHZE 2 FDC and RHZE 4 FDC lies in the combination form of the preparation, where 4 FDC combines all four drugs in one tablet, while 2 FDC is given in separate but fixed dosage combinations. The combined use of OAT category 1 (RHZE) + Ethambutol and RHE + Levofloxacin was found in 5 patients (4.7%) respectively. The INH+E+R regimen was used by 9 patients (8.5%), while Rifampicin+Ethambutol+Pyrazinimide was used by 6 patients (5.7%). The treatment pattern of RHE + INH and OAT category 2 (RHE) was used by 4 patients (3.8%) respectively.

Table 2 Treatment Pattern

Types of OAT	Frequency (F)	Present (%)
Oatmeal 1 (RHZE 2 FDC)	42	39,6
Oatmeal 1 (RHZE 4 FDC)	31	29,2
OAT cat 1 (RHZE) + E	5	4,7
RHE + INH	4	3,8
INH+E+R	9	8,5
RHE+ Levofloxacin	5	4,7
Rifampicin+Ethambutol+Pirazinamid	6	5,7
Oatmeal 2 (RHE)	4	3,8
Quantity	106	100

Source: *Primary data, 2026*

4.1.3 Side Effects of OAT

Table 3 shows the types of side effects experienced by pulmonary tuberculosis patients. It is known that the most common side effect of OAT experienced by patients is the change of urine to redness because it is experienced by all patients (100%).

Table 3 Frequency Distribution of OAT Side Effects

Side Effects of OAT	Frequency (F)	Present (%)
Nausea vomiting	88	83,0
Tingling	24	22,6
Reddish Urine	100	100
Flu Syndrome	75	70,8
Skin rash	23	21,3

Source: *Primary data, 2026*

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4.1.4 ESO Severity

Based on table 4, it shows that the most drug side effects experienced by pulmonary tuberculosis patients are moderate (getting additional therapy) with a total of 60 patients (56.6%), mild side effects (without getting additional therapy) as many as 39 patients (36.8%), and severe side effects (stop OAT) as many as 7 patients (6.6%).

Table 4 ESO Severity Frequency Distribution

Severity ESO	Frequency (F)	Present (%)
Lightweight	39	36,8
Medium	60	56,6
Weight	7	6,6
Quantity	106	100

Source: *Primary data, 2026*

4.2 Discussion

The characteristics of pulmonary tuberculosis patients at Bhina Bhakti Husada Rembang Hospital are dominated by productive age, in line with reports by the World Health Organization and the Ministry of Health of the Republic of Indonesia that tuberculosis is more common in the active age group. The majority of patients were male, had a sub-normal weight, and had a high school education. The length of treatment varies, with most side effects appearing in the first 1–3 months of therapy, suggesting that the initial phase of treatment is a period that is prone to the occurrence of side effects.

The results of the study showed that most pulmonary tuberculosis patients underwent therapy using first-line Anti-Tuberculosis Drugs (OAT) in accordance with the national provisions in the DOTS program. The treatment regimen applied consisted of a combination of isoniazid, rifampicin, pyrazidine, and ethambutol (RHZE) in the intensive phase, followed by a combination of isoniazid and rifampicin (RH) in the advanced phase. Some patients have allergies so they get levofloxacin and ethambutol treatment separately. The treatment pattern is in line with the National Guidelines for Tuberculosis Management issued by the Ministry of Health of the Republic of Indonesia, which emphasizes the use of combination therapy to reduce the risk of drug resistance and increase treatment success. This is in line with the findings of Verencia et.al who stated that the use of combination OAT is a standard in the management of pulmonary tuberculosis (Verencia et al., 2021). In addition to the main therapy, some patients also receive additional treatment in the form of vitamin B6 (pyridoxine) as a preventive measure against the side effects of neuropathy that can be caused by the use of isoniazid. The administration of pyridoxine is in accordance with clinical recommendations and is commonly used as supportive therapy in patients undergoing TB treatment.

Based on the findings of the study, almost all pulmonary tuberculosis patients experience complaints of side effects while undergoing OAT treatment. The most commonly reported side effects were nausea and vomiting, which were experienced by the majority of respondents. This suggests that disorders of the gastrointestinal system are the most dominant side effects, especially in the early stages of OAT therapy. The findings are in line with Nurhikma's research which states that nausea and vomiting are the most common complaints found in pulmonary tuberculosis patients as many as 15 people (71.5%). This condition is related to irritation of the gastric mucosa as well as the pharmacological effects of drugs such as isoniazid and pyrazanide on the gastrointestinal tract. These side effects are generally

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temporary and can be managed through symptomatic therapy and medication timing (Nurhikma et al., 2021). Urine discoloration to redness was found in all patients in this study. This condition is an effect of the use of rifampicin and is physiological and harmless. Rifampicin contains a red-orange pigment and is excreted through urine, sweat, and other body fluids. This is consistent with research (Oliviera) et al., 2020) and the guidelines of the Ministry of Health of the Republic of Indonesia which affirm that the change in urine color due to rifampicin does not indicate toxicity and does not require discontinuation of treatment (Ministry of Health of the Republic of Indonesia, 2025). In addition, some patients experience complaints of tingling. This symptom is related to the occurrence of peripheral neuropathy which is generally caused by the use of isoniazid due to impaired metabolism of vitamin B6. Previous research has shown that peripheral neuropathy is quite common, especially in patients with poor nutritional status or no pyridoxine supplementation (Laíse, 2022). Another side effect found is flu syndrome, which is characterized by the appearance of symptoms such as fever, cough, shortness of breath, headache, pain. Flu syndrome is generally associated with the use of rifampicin and appears in the early phases of treatment. This is in line with previous research that the most common side effects in the first and second months are fever, nausea, vomiting, dizziness, and joint pain (Nurhikma et al., 2021). Reactions in the form of skin rashes are also found in some patients. These vary from mild rashes to severe reactions that in certain conditions require temporary or permanent discontinuation of OAT therapy. These findings are in line with Soares' research et.al which states that hypersensitivity reactions in the skin are one of the causes of discontinuation of OAT therapy, although the frequency is lower than the effect on the gastrointestinal tract (Laíse, 2022).

Based on the grouping of the severity of side effects, the majority of patients experienced side effects in the moderate category, followed by the mild and severe categories. Mild side effects are generally nausea and vomiting, discoloration of urine to redness, and mild flu complaints that do not interfere with daily activities and do not require adjustment of treatment regimen, Side effects of moderate severity are the most common categories. This condition is characterized by more intense nausea and vomiting, flu syndrome that is quite disruptive to the patient's activities, and tingling complaints that require additional interventions such as vitamin B6 supplementation. Severe side effects are found in only a small percentage of patients and are generally associated with severe hypersensitivity reactions, such as skin rashes that require discontinuation of OAT therapy. This is in line with previous research, which stated that the occurrence of severe side effects is relatively rare, but has a significant impact on treatment continuity and can increase the risk of therapy failure if not treated optimally (August) et.al, 2023).

5. Concluding Remarks and Recommendation

Based on the results of the study, the therapy pattern in pulmonary tuberculosis patients was dominated by the use of OAT category 1 RHZE 2 FDC which was used by 42 patients (39.6%), followed by OAT category 1 RHZE 4 FDC as many as 31 patients (29.2%). These findings suggest that most patients have received treatment in accordance with national guidelines for tuberculosis control. The most common type of OAT side effect experienced by patients was nausea and vomiting, which occurred in 88 patients (83.0%). In addition, all patients (100%) experience a change in urine color to redness, which is a typical and physiological side effect of rifampicin use. Based on severity, the most OAT side effects were included in the moderate category, which was 60 patients (56.6%), followed by the mild category as many as 39 patients (36.8%), and the severe category as many as 7 patients (6.6%).

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