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SIDE EFFECTS OF SECOND-LINE ANTITUBERCULOSIS DRUGS IN MULTI-DRUG RESISTANCE (MDR) TUBERCULOSIS PATIENTS

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ABSTRAK

Tuberkulosis resistan obat (MDR TB) disebabkan oleh strain Mycobacterium tuberculosis yang kebal terhadap isoniazid dan rifampisin—dua obat anti-TB paling efektif. Lama waktu pengobatan dan kompleksitas regimen terapi sering menjadi penyebab rendahnya kepatuhan pasien, yang berdampak pada tingginya angka MDR TB dan rendahnya keberhasilan pengobatan, khususnya di Indonesia. Penelitian ini menganalisis pola penggunaan obat pada 52 pasien MDR TB di RSUP Dr. Mohammad Hoesin Palembang, menggunakan metode total sampling berdasarkan data rekam medis periode Oktober 2018 hingga Desember 2019. Data dianalisis secara deskriptif menggunakan SPSS versi 25. Efek samping yang paling umum dilaporkan adalah lemas, mual, dan muntah (84,6%), diikuti oleh artralgia, hiperurisemia, dan gangguan pendengaran (42,3%). Efek samping berat lebih banyak ditemukan pada pasien dengan regimen jangka pendek (40,4%) dibandingkan dengan jangka panjang (7,7%). Lemas, mual, dan muntah merupakan efek samping yang paling sering terjadi pada pasien MDR TB.

ABSTRACT

Side Effects of Second Line Antituberculosis Drug in Multi-Drug Resistance Tuberculosis Patients. Multidrug-resistant tuberculosis (MDR TB) is caused by Mycobacterium tuberculosis strains resistant to isoniazid and rifampicin—the most potent anti-TB drugs. Prolonged treatment duration and complex drug regimens often lead to poor adherence, contributing to high MDR TB incidence and low treatment success rates, particularly in Indonesia. This study analyzed drug utilization patterns in 52 MDR TB patients at Dr. Mohammad Hoesin Hospital Palembang, using total sampling based on medical records from October 2018 to December 2019. Data were analyzed descriptively with SPSS v25. The most common side effects reported were weakness, nausea, and vomiting (84.6%), followed by arthralgia, hyperuricemia, and hearing loss (42.3%). Severe side effects were more prevalent in the short-term regimen group (40.4%) compared to the long-term group (7.7%). Weakness, nausea, and vomiting were the most frequently observed side effects in MDR TB patients.

INTRODUCTION

Tuberculosis remains a major focus in global health issues, one of the top ten causes of death globally and the leading cause of death from a single infectious agent(1). The WHO estimates that a quarter of the world is infected with Mycobacterium tuberculosis. MDR TB is an infection of MTB microorganisms that experience resistance to rifampicin and isoniazid either followed by other types of antituberculosis drugs or without other antituberculosis drugs(2). The prevalence of MDR TB in 2019 globally is 78% around 465,000 people, while in Indonesia 6.2-12 people per 100,000 population, of the 206,030 people who were detected cases of MDR TB in 2019 around 177,099 received treatment.[1] This high result makes Indonesia in the top 10 countries experiencing overlapping TB, TB with HIV and MDR TB.[1]

Resistance to anti-tuberculosis drugs is a major obstacle in TB control. Despite global efforts to control the incidence of multidrug-resistant TB, treatment success has not yet reached the target. The MDR TB treatment success target is 75% or more, but the latest treatment success rate shows that the treatment success rate is still 57%. In Indonesia, the success of treatment is still below 50%, with almost 21% loss to follow-up (LTFU). Long duration of treatment, polypharmacy, painful daily intramuscular injections, and significant side effects (including ototoxicity) are problems that burden patients and patients' families. Since 2016, growing research has forced the WHO and other agencies to urge the replacement of longer regimens with shorter, easier-to-take, better-tolerated oral treatment regimens.[3,4] Therefore, a short-term regimen with a shorter duration is formed but uses more than long-term regimens. However, some studies, especially in South Korea, actually prefer to use a long-term regimen because it has been supported by in-depth research rather than short-term regimens that tend to cause more side effects than long-term regimens.[5] This is also in line with research by Pratiwi, et al in 2016 that major side effects were found in MDR TB patients who took the short-term regimen.[6] Although WHO states that long-term regimens are proven to increase the likelihood of cure and reduce mortality, several cases show the occurrence of optic neuropathy, toxicity to severe psychological disorders in the form of depression, psychotic and suicidal ideation.[1,7] The main difference between long-term and short-term regimens for MDR-TB lies in the duration, complexity, and drugs involved in treatment. The short-term regimen lasts 9 to 12 months. It's designed to shorten treatment duration while still effectively addressing MDR-TB. The drugs are often newer or more potent, designed to target the resistant strains. The long-term regimen can last from 18 to 24 months. Long-term regimens are more traditional and involve a more extended course of treatment to ensure that the resistant bacteria are fully eradicated.[8,11,15]

Looking back at the high incidence and low success of MDR TB treatment in Indonesia. Therefore, optimal management and evaluation of side effects of MDR TB treatment is very important. However, the latest data on side effects from long-term and short-term regimens is still minimal in Indonesia, especially in the city of Palembang. Given that it is very important to know this, it is behind the research conducted by the author.

METHOD

This research method is descriptive in the form of a study of drug use patterns. This study used a total sampling of n = 52 confirmed patient medical records based on bacteriological examination, TCM TB or Xpert MTB / RIF had MDR TB and had an age range of 18-65 years from October 2018 to December 2019. Patients who have extrapulmonary MDR TB infection, pre / XDR,

moved treatment location from Dr. Mohammad Hoesin Hospital Palembang, changed treatment regimens, dropped drugs and had a history of HIV / AIDS TB coinfection, hormonal disorders, heart disease, psychiatric disorders and postoperative were excluded.

RESULTS

This study used 52 medical record samples from MDR TB patients. From the results of the study, it was found that minor side effects were more experienced by MDR TB patients than major side effects, amounting to 27 patients (51.9%).

Table 1. Side Effects of Second Line Anti-tuberculosis Drugs on MDR TB Patients Based On Category

	Category	(n)	(%)
Side Effects	Major	25	48,1
	Minor	27	51,9
	Total	52	100

In this study, it was found that patients on short-term regimens experienced more side effects. In short-term regimens, major side effects are more common than in long-term regimens. Long-term regimens found minor side effects were more common, namely 9 people (17.3%). While on the short-term regimen, major side effects were more common, namely 21 people (40.4%).

Table 2. Side Effects of Second Line Anti-tuberculosis drugs on MDR TB Patient based on Regimens

Regimens	Category	Side Effects			
		Major		Minor	
		n	%	n	%
	Long-term	4	7,7	9	17,3
	Short-term	21	40,4	18	34,6
	Total	25	48,1	27	51,9

Table 3 presents data on side effects that occur based on comorbid DM obtained in DM patients, minor side effects occur more, namely as many as 7 people (13.5). In non-DM patients, major and minor side effects obtained equivalent results, namely as many as 20 people experienced minor side effects and 20 people experienced major side effects.

Table 3. Side Effects of Second Line Anti-tuberculosis drugs on MDR TB Patient based on Diabetes Mellitus

		Side Effects			
	Category	**Major**		**Minor**	
		n	**%**	**n**	**%**
Diabetes Mellitus	DM	5	9,6	7	13,4
	NON DM	20	38,5	20	38,5
	Total	25	48,1	27	51,9

Data on side effects that occur based on BMI in the table 4, it is found that major side effects are more common in the underweight than in each other group. In addition, side effects were more common in MDR TB patients with underweight than in normal and overweight groups, which was 33 people (63.5%). From October 2018- December 2019, no obese patients were found.

From the 52 samples obtained, 44 patients (84.6%) complained of experiencing weakness, nausea and vomiting during treatment. The incidence of weakness, nausea, and vomiting occupied the most frequent incidence of side effects in this study. The most common side effects after that were hearing loss and arthralgia and hyperuricemia as many as 42.3% or 22 patients experienced it.

Since Indonesia has a lower treatment success rate (<50%), exploring whether side effects contribute to loss to follow-up (LTFU) could add valuable insight.

Although TB is a disease that has been known for a long time, until now TB remains a major health problem throughout the world. MDR-TB management using a second-line regimen is known to have far more side effects than the first-line regimen. This can affect the reactions that occur in patients both in terms of disease severity, quantity of treatment and much longer patient hospitalization.[8] Side effects that occurred in MDR TB patients for the period October 2018-December 2019 at Dr. Mohammad Hoesin Hospital Palembang included weakness, nausea, vomiting, arthralgia, hyperuricemia, ototoxic, burning, peripheral neuropathy, optic neuritis, hematological disorders, liver function disorders, dermatological disorders, electrolyte disorders, and kidney function disorders. Those side effects can contribute to LTFU (Loss to Follow-Up) patients. Several studies identified that LTFU in MDR TB Patients can occur by long duration of treatment, high pill burden, and side effects. A study in India reported adverse drug effects as an important barrier to treatment adherence. Side effects such as vomiting, severe headache, vertigo, and psychiatric conditions were an important reason to discontinue treatment.[4-6,13,20]

Anti-tuberculosis drug side effects are divided into major and minor side effects. Major side effects are complaints experienced by patients that require temporary or permanent discontinuation of Anti-tuberculosis drugs, while minor side effects are complaints experienced by patients that can be overcome by adjusting diet, dosage, or adding symptomatic drugs without stopping anti-tuberculosis drugs. Major side effects consist of hearing loss, dizziness, icteric hepatitis without other causes, dermatological disorders, vomiting and confusion, impaired kidney function, heart disorders, optic neuritis, major depression/suicidal ideation, psychotic symptoms, and hematological disorders. Minor side effects include arthralgia/hyperuricemia, weakness, nausea, vomiting, burning, peripheral neuropathy, hypothyroidism, sleep disorders, gastritis and abdominal pain, electrolyte disorders, headaches.[9]

Table 4. Major and Minor Side Effects Using Second Line Anti-tuberculosis Drugs in MDR TB Patients

Variable	Side Effects				Total
	Yes		No		
	N	%	n	%	n
Arthralgia dan Hyperuricemia	22	42,3	30	57,7	52
Weakness, Nausea, and Vomiting	44	84,6	8	15,4	52
Burning	2	3,8	50	96,2	52
Peripheral Neuropathy	6	11,5	46	88,5	52
Optical Neuritis	3	5,8	49	94,2	52
Hematological Disorder	6	11,5	46	88,5	52
Hearing Disorder	22	42,3	30	57,7	52
Hepatic Disorder	7	13,5	45	86,5	52
Dermatological Disorder	3	5,8	49	94,2	52
Electrolyte Disorder	18	34,6	34	65,4	52
Kidney Disorder	10	19,2	42	80,8	52
Headache	0	0	52	100	52

The most common side effects obtained from the results of this study were weakness, nausea, and vomiting which occurred in 44 patients (84.6%). This result is similar to the results of Munir et al's research which states the most common side effect is digestive disorders at 20.8%(10). Mandhav in his research also got similar results where side effects that often occur are intestinal disorders in the form of nausea, vomiting, and decreased appetite.[11] This occurs because the second-line drug in MDR TB treatment stimulates emetic stimuli with various mechanisms ranging from stimulating the abdominal vagal, disrupting the vestibular system and CNS.[12] However, the specific mechanism is still unclear.

The next most common side effects are arthralgia/hyperuricemia and ototoxicity or hearing loss. This result is also similar to the research of Sri et al and Bhardwaj which states the side effects of hyperuricemia and hearing loss are often encountered after nausea, vomiting.[10,13] Side effects of nausea and vomiting are usually caused by pyrazinamide, ethambutol, and ethionamide. These side effects usually do not stop treatment but are reduced doses, divided doses or given drugs to overcome symptoms in the form of domperidone or proton pump inhibitors.[14] Hearing loss is closely related to the administration of injectable aminoglycoside groups.[13] Initial exposure to kanamycin or capreomycin injection will affect the cochlea. Continuous exposure leads to progressive deterioration.[14] Ototoxicity has a permanent nature therefore the management of this side effect is a temporary or permanent cessation of kanamycin or capreomycin which makes it one of the major side effects.[13,15] The mechanism of ototoxicity by aminoglycosides is due to disruption of mitochondrial protein synthesis and free radical accumulation followed by destruction of hair cells in the cochlea.[16]

Side effects of anti-tuberculosis drugs in the form of arthralgia and hyperuricemia that occur in therapy are usually caused by the administration of pyrazinamide, levofloxacin, and ethambutol. Pyrazinamide is a powerful uric acid retention agent that causes a decrease in renal clearance of more than 80% of uric acid at 300 mg/day to cause hyperuricemia. Similarly, ethambutol but the effects that occur are not as severe as when giving pyrazinamide.[17] It is reported that 43% to 100% of patients taking pyrazinamide have hyperuricemia/arthralgia either given pyrazinamide alone or

in combination.[18,19] Minor side effects in this study were more than major side effects. This is in line with previous studies in South Korea that found major side effects occurred in 21.1% of the population alone.[20]

Table 5. Side Effects Based on Diabetes Mellitus

		Side Effects				Total	
		Major		Minor			
	Category	N	%	n	%	n	%
BMI	*Underweight*	16	30,8	17	32,7	33	63,5
	Normal	8	15,4	9	17,3	17	32,7
	Overweight	1	1,9	1	1,9	2	3,8
	Obese	0	0	0	0	0	0
	Total	25	48,1	27	51,9	52	100

In the use of short-term regimens major side effects are more common, this is in line with the research of Nunn et al which states that grade 3 to 5 side effects are more common in patients with short-term regimens than long-term regimens with a proportion of 48.2% on short-term regimens and 45.4% on long-term regimens, this is related to short-term regimens having more combinations of anti-tuberculosis drugs than long-term regimens so that they can cause much greater inter-drug interactions and increase the risk of severe side effects.[21,22]

In DM patients minor side effects are more common, while in patients without comorbid DM has the same probability for the occurrence of side effects either minor or major. This is in line with the assessment of Reviono, et al who stated that side effects that occur in DM patients are minor.[15] However, it is not in line with previous studies that stated severe side effects are more common in MDR TB patients who have comorbid DM.[23] This result itself does not have too big a difference, because DM patients who experience MDR TB are few and also the occurrence of these side effects in these patients is influenced by many factors, such as the late start of treatment.[24]

The study also found that patients who were underweight experienced more side effects. Major side effects were also found more in the underweight group. This is also similar to Park et al's research which states that TB patients who are underweight are more at risk of severe side effects and increased morbidity and mortality.[25] This is because in underweight patients decrease in fat mass and energy protein malnutrition, will make the amount of binding protein (protein binding*)* decrease and cause more levels of drugs in free form and make pharmacological activity increase and can cause the risk of side effects to be greater.[26] In addition, being underweight can also affect the immune system, and make the patient's immunity decrease so that they are more susceptible to other infections.[27] This makes underweight will aggravate the clinical condition of MDR TB patients and increase the risk of death 2x greater than normal and overweight BMI groups.[28]

Since nausea, vomiting, and hearing loss are common side effects of many second-line drugs used in MDR-TB treatment, some actions are needed to reduce these adverse effects. Anti-emetic, dosing adjustment, routine follow-up, early detection, regular assessment, supportive care, and patient education can be used as prophylactic intervention and monitor treatment.[5,12,16]

Given the high incidence of nausea, vomiting, and hearing loss, should there be routine monitoring or prophylactic interventions for these side effects?

MDR TB patients in this study found the most common side effects were weakness, nausea, and vomiting experienced by 44 people (84.6). The next side effects that often occur are arthralgia and hyperuricemia with a proportion of 42.3% and hearing loss with the same proportion, which is 42.3%. Minor side effects were more prevalent with a proportion of 51.9%. In DM patients, minor side effects were more common, namely 7 people (13.5%) while in DM patients minor side effects occurred in 5 people (10.8%). In non-DM patients, minor and major side effects occurred with the same probability, which is 38.5%. In underweight patients, side effects were more common than other BMI groups with a proportion of 63.5%. On short-term regimens, major side effects were more common than minor side effects, with a proportion of 34.6% in minor side effects and 40.4% in major side effects. While in long-term regimens minor side effects are much more common than major side effects with a proportion of 17.3% in minor side effects and 7.7% in major side effects. Short-term regimens experienced more major side effects than long-term regimens with a proportion of 40.4% on short-term regimens and 7.7% on long-term regimens.

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