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Compliance Level and Side Effects in the Treatment of Tuberculosis Patients: A Study from Indonesia

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Abstract

Indonesia has the second largest Tuberculosis (TB) burden in the world. One of the solutions to reduce this prevalence is medication compliance and avoiding side effects. However, compliance level and side effects data on TB patients in Indonesia are still limited. Therefore, the study aimed to determine compliance levels and medication side effects in tuberculosis susceptible drugs patients. Medication Morisky Adherence Scale-8 (MMAS-8) and Naranjo algorithm scale were used to determine the compliance level and the side effects, respectively. Seventy-six patients were involved in this study (male 64.47%, mean age 45.68 y.o, and 98.68% living with family). The compliance level of low, medium, and high were 5.28%, 40.79%, and 53.93%, respectively. Thirty-five (46.05%) patients experienced side effects, which involved a high probable category (37.15%) was tingling, a probably category (42.85%) was nausea, itch, myalgia, and tingling, and a possible category (20.01%) was cough and myalgia. We didn't find any correlation between compliance with age, sex, education level, and occupations. However, education level slightly correlated with compliance (p 0.066). The compliance level is still low, provides an education and side effects prevention and treatment may increase the compliance level. These compliance and side effects data give a solution to reduce the prevalence of TB in Indonesia.

Keywords: Compliance, MMAS-8, Naranjo Algorithm, Side Effects, Tuberculosis

1. Introduction

Tuberculosis (TB) is a disease caused by the *Mycobacterium tuberculosis* and the second cause of mortality from infectious diseases group (WHO, 2022). The prevalence worldwide people fell ill of TB reached 10.6 million (WHO, 2021). Until recently, TB is still a global burden, especially for a developing country, including Indonesia, which placed the second largest contributor after India (WHO, 2023). In Indonesia, the TB incidence rate for drugs susceptible (non-MDR-TB) reached 354 per 100.000 populations and 10 per 100.000 populations for MDR-TB (WHO, 2022). Compliance with the medications is one of the determinant keys to eradicating TB and reducing the incidence of multidrug-resistant TB (MDR-TB) (Sveinbjornsdottir., et al. 2024). However, this compliance will be reduced by the side effects of the TB medications (Awofeso, 2008; Lolong et al., 2023). Unfortunately, the

compliance level and side effects studies for TB medications are still limited in Indonesia. Therefore, we conducted a study on the compliance level and TB medication's side effects in Indonesian susceptible-drug TB patients.

2. Method

The study is a prospective cross-sectional study through direct interviews with the patients using the Medication Morisky Adherence Scale-8 (MMAS-8) for compliance and the Naranjo algorithm for drug side effects (Laghousi et al., 2023; Belhekar et al., 2014). This study was conducted in Ciamis General Hospital from January-April 2023. The patient sampling method used was purposive sampling. The inclusion criteria for the patients were diagnosed with TB susceptible drugs, outpatients, age ≥ 18 y.o, and agreed to be a respondents by signing informed consent. All the procedures of this study were approved by the Ethical Research Health Committee of Bakti Tunas Husada University with number 034/E.01/KEPK-BTH/III/2023. The data was analyzed using SPSS version 22 with the Chi-square method. The significant level is at a P value of 0.05.

3. Results

Seventy-six patients were involved in this study with domination of males, 46-65 y.o, elementary school education, unemployment, and living with family members (Table 1). Moreover, 13.6% of this population has no health insurance to cover the medications cost. The results of the compliance level for low, moderate, and high adherence were 5.26%, 40.79%, and 53.95%, respectively (Table 2). Moreover, no correlation between compliance with age, sex, education level, and occupation. However, education level slightly correlated with the compliance (p 0.066) (Table 3). Based on the Naranjo algorithm, myalgia, itchy, shortness of breath, and tingling are highly probable side effects category due to TB medications. Meanwhile, nausea and cough side effects involve probable and possible categories, respectively (Table 4).

Table 1: Patients Demographic

Patients Characteristic	number	%	
Age	19-25 y.o	14	18.42
	26-35 y.o	9	11.84
	36-45 y.o	7	9.21
	46-55 y.o	17	22.37
	56-65 y.o	16	21.05
	≥ 66 y.o	13	17.11
Sex	Male	49	64.47
	Female	27	35.53
Living with family	Yes	75	98.68
	No	1	1.32
Education	Elementary school	28	36.84
	Junior High School	22	28.95
	Senior High School	17	22.37
	Bachelor	8	10.53
	Postgraduate	1	1.32
Occupations	Government Employees	6	7.89
	Entrepreneur	33	43.42
	Teacher	1	1.32
	Farmer	3	3.95
	Housewife	14	18.42
	Unemployment	19	25.00
Insurance ownership	Yes	66	86.84
	No	10	13.16
Total	76	100	

Table 2: Compliance Level Based on MMAS-8 Questionnaire

No	Compliance Level	number	%
1	Low adherence	4	5.26
2	Moderate adherence	31	40.79
3	High adherence	41	53.95
Total		76	100

Table 3: Relationship between Compliance Level and Patients Characteristic

	Characteristic	Compliance Level			p-value (95% CI)
		Low adherence (%)	Moderate adherence (%)	High adherence (%)	
Age	19-25 y.o	0.00%	13.16%	5.26%	0.315
	26-35 y.o	1.32%	2.63%	7.89%	
	36-45 y.o	1.32%	3.95%	3.95%	
	46-55 y.o	1.32%	5.26%	15.79%	
	56-65 y.o	1.32%	9.21%	10.53%	
	≥66 y.o	0.00%	6.58%	10.53%	
Sex	Male	2.63%	27.63%	34.21%	0.767
	Female	2.63%	13.16%	19.74%	
Living with family	Yes	5.26%	40.79%	52.63%	0.649
	No	0.00%	0.00%	1.32%	
Education level	Elementary school	2.63%	14.47%	19.74%	0.066
	Junior High School	0.00%	10.53%	18.42%	
	Senior High School	0.00%	14.47%	7.89%	
	Bachelor	2.63%	1.32%	6.58%	
	Postgraduate	0.00%	0.00%	1.32%	
Occupations	Government employees	0.00%	0.00%	7.89%	0.401
	Entrepreneur	1.32%	23.69%	18.42%	
	Unemployment	2.63%	9.21%	13.16%	
	Teacher	0.00%	0.00%	1.32%	
	Farmer	0.00%	2.63%	1.32%	
	Housewife	1.32%	5.26%	11.84%	
Insurance	Yes	3.95%	34.21%	48.69%	0.127
	No	1.32%	6.58%	5.26%	

Table 4: Side effects based on Naranjo algorithm

Category	Side Effects	n	%
Possible	Myalgia, cough	7	20
Probable	Nausea, tingling, itchy, myalgia	15	42.85
Highly Probable	Myalgia, itchy, shortness of breath, tingling	13	37.15

4. Discussion

The demographic data indicates that 98.68% of TB patients live with family members such as their father and mother, as well as other family members (Table 1). This is a dominant factor in the rapid spread of TB in Indonesia, necessitating a reorganization of population density in areas to reduce the acceleration of TB transmission (Narasimhan et al., 2013). Additionally, TB patients predominantly have low education levels and are unemployed

(Table 1). Low education levels result in limited critical thinking skills and can hinder the effectiveness of disseminating TB prevention information and compliance with TB treatment (Nezenega et al., 2020). Meanwhile, unemployment leads to smokers, alcohol abuse, and the inability to meet the nutritional needs of the community, resulting in decreased immunity or community health and making individuals more susceptible to infection (Przybylski et al., 2014). Improving human resources through increased access to education and facilitating access to suitable employment is fundamental in addressing this issue. Another factor impacting the increase in TB is the lack of health insurance for TB patients (Table 1), requiring individuals to bear the treatment costs themselves. Based on these factors, TB treatment becomes the primary focus as an eradication measure by covering all treatment costs for TB patients.

In the compliance study, the findings are that the compliance rate is only about 53.95% (Table 2), with the remaining TB patients experiencing forgetfulness in taking medication, which can affect the success of treatment. The most significant factor influencing this non-compliance is the level of education (Table 3). Therefore, increasing education through facilitating access to education and comprehensive TB-related information is crucial in improving patient compliance with medication (Nezenega et al., 2020; Yani et al., 2022).

In the study on side effects, the findings are that muscle pain or stiffness, skin itching, tingling, and shortness of breath are the main side effects of treatment for drug-sensitive TB (not MDR). Approaches to preventing side effects such as providing pyridoxine for tingling are essential (Mafukidze et al., 2015; Bhargava & Bhargava, 2018), and consuming plenty of water or eating bananas can prevent nausea or vomiting (Central TB Division, 2016). Meanwhile, treatment approaches are used for side effects that cannot be prevented, such as using antihistamines or topical corticosteroids for mild to moderate itching, and using topical pain relievers for myalgia (Central TB Division, 2016). Providing information or guidance in the form of a pocketbook regarding side effects and self-management techniques is crucial to be provided to patients.

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Informed Consent Statement/Ethics approval: All subjects gave their informed consent for inclusion before they participated in the study. The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Ethics Committee of Bakti Tunas Husada University with number 034/E.01/KEPK-BTH/III/2023.

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