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# ANALYSIS SUCCESS RATE OF BPAL/M THERAPY FOR DRUG RESISTANT TUBERCULOSIS

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## ABSTRAK : ANALISIS TINGKAT KEBERHASILAN TERAPI PADUAN BPAL/M PADA TUBERKULOSIS RESISTEN OBAT

Latar Belakang: Tuberkulosis (TB) adalah penyakit yang dapat dicegah dan biasanya dapat disembuhkan. Tuberkulosis menyebabkan sekitar 1,25 juta kematian di dunia pada tahun 2023. Secara global, diperkirakan terdapat 450 ribu kasus baru tuberkulosis *multi-drug resistant* (MDR) atau tuberkulosis *rifampicin resistant* (RR) pada tahun 2021. Tantangan dalam pengobatan Tuberkulosis Resisten Obat (TB-RO) diantaranya adalah jangka waktu pengobatan yang lebih lama menggunakan OAT lini kedua dengan berbagai efek samping yang memengaruhi kepatuhan berobat pasien. Oleh karena itu, pengobatan yang lebih singkat dengan lebih sedikit obat sangat dibutuhkan untuk mengatasi tantangan tersebut. Sejak tahun 2022, WHO telah mengumumkan pengobatan dengan paduan Bedaquiline, Pretomanid, Linezolid, dan Moksifloksasin (BPaL/M) untuk mengobati pasien TB-RO selama enam bulan.

Tujuan: Mengetahui karakteristik pasien TB-RO dan untuk mengetahui tingkat keberhasilan terapi pada pasien TB-RO yang mendapatkan pengobatan paduan BPaL/M di Rumah Sakit Umum Daerah Dr. H. Abdul Moeloek Provinsi Lampung.

Metode: Penelitian dilakukan menggunakan metode observasional dengan penyajian analisis deskriptif.

Hasil: Karakteristik penderita tuberkulosis resisten obat terbanyak pada kelompok usia produktif yaitu rentang usia 20–44 tahun dengan jumlah 15 pasien atau sebesar 46%. Kelompok resisten primer dengan jumlah 19 pasien atau sebesar 58%. Karakteristik hasil uji kepekaan obat terbanyak pada kelompok resisten rifampicine dengan jumlah 21 pasien atau sebesar 64%. Median konversi sputum pada akhir pengobatan bulan ke-1, dengan tingkat keberhasilan terapi sebesar 83.9%.

Kesimpulan: Paduan BPaL/M menghasilkan konversi sputum yang cepat sehingga sangat efektif dan dapat menjadi pilihan terapi bagi pasien TB RR/MDR/pre-XDR pada fasilitas kesehatan di Indonesia.

Saran: Penelitian selanjutnya dapat membandingkan efektifitas terapi paduan BPaL/M, paduan pengobatan 9 bulan, dan paduan pengobatan jangka panjang dalam tingkat keberhasilan dan waktu konversi sputum.

Kata Kunci: Keberhasilan Terapi, Paduan BPaL/M, Tuberkulosis Resisten Obat.

### **ABSTRACT**

Background: Tuberculosis (TB) is a preventable and usually curable disease. In 2023, tuberculosis causes an estimated 1.25 million deaths worldwide. Globally, there are an estimated 450,000 new cases of multi-drug resistant (MDR) tuberculosis or rifampicin resistant (RR) tuberculosis by 2021. Challenges in the treatment of drug-resistant tuberculosis (DR-TB) include a longer treatment period using second-line OAT with various side effects that affect patient treatment adherence. Therefore, shorter treatment with fewer drugs is needed to overcome these challenges. Since 2022, WHO has announced treatment with Bedaquilline, Pretomanid, Linezolid, and Moxifloxacin (BPaL/M) to treat drug-resistant tuberculosis (DR-TB) patients for six months.

Purpose: Knowing characteristics of DR-TB patients from 2024 to 2025 and to determine the efficacy of therapy in DR-TB patients who received BPaL/M treatment at Dr. H. Abdul Moeloek General Hospital, Lampung Province.

Method: This study was an observational research with descriptive analysis.

Result: The characteristics of DR-TB patients were mostly in the productive age group, range 20-44 years with a total of 15 patients or 46%. Primary resistant group with a total of 19 patients or 58%. The characteristics of

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drug sensitization test results were mostly in the rifampicine resistant group with a total of 21 patients or 64%. Median sputum conversion at the end of first month treatment, with the treatment success rate was 83.9%.

Conclusion: BPaL/M regimen has shown rapid sputum conversion, therefore leading to a highly effective treatment option for patients with RR/MDR/pre-XDR TB in health facilities in Indonesia.

Suggestions: Future studies might compare the effectiveness of BPaL/M regimen, 9-month regimen, and long-term regimen based on success rate and sputum conversion time.

Keywords: Efficacy of Therapy, BPaL/M Regimen, Drug Resistant Tuberculosis.

### INTRODUCTION

Tuberculosis (TB) is a preventable and usually curable disease. Based on data from the World Health Organization (WHO), it is estimated that there are 10.8 million people with TB worldwide in 2023, or 134 cases per 100,000 population. Tuberculosis caused approximately 1.25 million deaths in the world in 2023. In Indonesia. TB cases in 2023 were recorded at 821,200 cases with 23,858 TB patients dying.2 Data from WHO's Global TB Report 2023, shows that in 2022 the estimated number of MDR-TB cases was 410,000 cases, with a death rate of 160,000 cases. Tuberculosis (TB) is a preventable and usually curable disease. Tuberculosis is a infectious disease caused by a bacterial infection of Mycobacterium tuberculosis (MTB). The disease is transmitted from one patient to another through nucleus droplets containing the organism and spread mainly through coughing. Mycobacterium tuberculosis most commonly infects the lungs, but can also infect almost any organ system, including the lymph nodes, central nervous system, bones, urinary tract and gastrointestinal tract. Mycobacterium tuberculosis is rod-shaped, without spores and without capsules, measuring 0.3 - 0.6 µm wide and 1- 4 µm long. The wall of Mycobacterium tuberculosis is very complex, consisting of a high fat layer (60%). The main components of the cell wall are mycolic acid, complex-waxes, dimvcolic trehalose called cord factor, and mycobacterial sulfolipids which play a role in virulence (WHO, 2025; Kemenkes RI, 2023; PDPI 2021). It is often not appreciated that the impact of TB does not end at treatment completion. and post-TB complications will profoundly impact on the wellbeing of many survivors. Up to 60% will have measurable respiratory impairment with possibly severe economic, social and psychological consequences. Patients surviving TB have a four-fold risk of lung cancer and may experience acute exacerbations of their lung disease, analogous to exacerbations in other chronic lung diseases (e.g., COPD) (Janssen, 2025).

Drug-resistant tuberculosis (DR-TB) is an infection of Mycobacterium tuberculosis (MTB) that has been resistant to at least one type of first-line OAT, which consists of rifampicin, isoniazid, pyrazinamide. and ethambutol. The main mechanisms of acquired drug resistance in Mycobacterium tuberculosis can be divided into several categories, such as the mutation or modification of drug targets, the inability to activate prodrugs due to mutations that cause loss of function, and enzymatic inactivation of drugs. The WHO has defined five categories to classify cases of drug-resistant (DR) TB: monoresistant TB, multidrug resistant TB (MDR-TB), rifampicin resistant TB (RR-TB), extensively drug resistant TB (XDR-TB), and pre-XDR-TB. Treatment of MDR-TB and XDR-TB is a major challenge for global efforts due to limited treatment options, duration of therapy. and high rates of treatment failure (Brode 2022; Green, 2013: Gualano 2025).

The treatment of DR-TB has been developing with administration of oral regimens that are more effective, shorter, less toxic, and more tolerable. Therefore, these regimens are aimed at improving treatment adherence and outcomes. In WHO announced 2022. the Bedaguiline. Pretomanid, Linezolid, and Moxifloxacin (BPaLM) treatment to treat patients with DR-TB for six months. BPaLM treatment represents a new promising approach to improving adherence and effectiveness of treatment for patients with DR-TB. TB treatment focuses on individual patient cure targets and minimizing the risk of Mycobacterium Tuberculosis (MTB) transmission to the surrounding environment so that effective TB treatment is expected to benefit patients and the community. This study aims to analyze the demographic features, average conversion time, and success rate of MDR/RR/Pre-XDR TB patients undergoing treatment using BPaLM therapy at Dr. H. Abdul Moeloek General Hospital, Lampung Province, Indonesia (Putra 2024).

#### RESEARCH METHODS

This study was an observational descriptive design. Secondary data were taken from the medical records of the Pulmonary Department of Dr. H. Abdul Moeloek General Hospital Lampung Province and the Tuberculosis Information System of the Indonesian Ministry of Health. A total of 33 patients diagnosed with drug-resistant pulmonary tuberculosis who completed the BPaL/M regimen for 26 weeks in the January 2024 to July 2025 period were sampled. Enrollment criteria included patients diagnosed with drug resistant pulmonary tuberculosis (DR-TB), including rifampicin resistant TB (RR-TB), Multidrug resistant TB (MDR-TB), preextensively drug-resistant TB (Pre-XDR TB), patients who received and completed the BPaL/M regimen (Bedaguiline, Pretomanid, Linezolid, ± Moxifloxacin) for 26 weeks, patients aged ≥14 years old, regardless of HIV status, patients with complete medical records available at Dr. H. Abdul Moeloek General Hospital and tuberculosis information system (SITB) of the Ministry of Health of Indonesia. Participants were excluded if patients with incomplete or missing medical record data, patients with resistance to fluoroquinolones who did not receive the proper BPaL modified regimen (without Moxifloxacin), patients who could not be evaluated for sputum conversion due to loss of follow-up or insufficient bacteriological examinations.

#### RESEARCH RESULT

Dr. H. Abdul Moeloek General Hospital Lampung Province is one of the advanced referral health facilities in Lampung Province that provides medical services to patients with drug-resistant tuberculosis. In the period of 2024 - 2025, there were 33 patients diagnosed with drug-resistant pulmonary tuberculosis who received BPaLM short-term regimen. Demographic data analysis was conducted to see the frequency and percentage based on patient characteristics, such as age, type of resistance, and drug sensitization test results.

Age

Tabel 1
The frequency distribution of age in patients diagnosed with drug-resistant pulmonary tuberculosis who received BPaL/M regimen at Dr. H. Abdul Moeloek General Hospital Lampung Province (2024-2025)

	Age	
20-44	45-59	>60
years old	years old	years old
15	10	8
	years old	20-44 45-59 years old

Age groupings are classified as follows: 20-44 years old, 45-59 years old and over 60 years old.

The purpose of grouping patients by age is to determine the prevalence of tuberculosis in certain age groups.

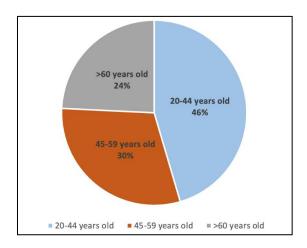


Diagram 1. The frequency distribution of age in patients diagnosed with drug-resistant pulmonary tuberculosis who received BPaL/M regimen at Dr. H. Abdul Moeloek General Hospital Lampung Province (2024-2025)

### Type of Resistance

There are two types of resistance in DR-TB: primary resistance and secondary resistance (Kemenkes RI 2023). The frequency of resistance types in patients diagnosed with drug-resistant pulmonary tuberculosis who received BPaL/M regimen at Dr. H. Abdul Moeloek General Hospital Lampung Province (2024-2025) can be seen in Table 2.

Tabel 2
The Frequency of resistance types in patients diagnosed with drug-resistant pulmonary tuberculosis who received BPaL/M regimen at Dr. H. Abdul Moeloek General Hospital Lampung Province (2024-2025)

_	Type of Resistance		
DR-TB patient	Primary	Secondary	
	Resistance	Resistance	
Number of Patient	19	14	

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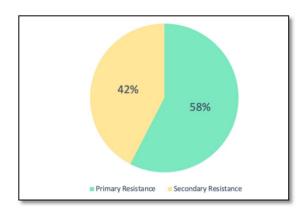


Diagram 2. The frequency of resistance types in patients diagnosed with drug-resistant pulmonary tuberculosis who received BPaL/M regimen at Dr. H. Abdul Moeloek General Hospital Lampung Province (2024-2025).

**Drug Sensitization Test** 

The criteria for patients who can be given BPaLM regimen are patients with RR/MDR TB. The results of the fluoroquinolone drug sensitivity test are used to determine the use of moxifloxacin, if there is resistance to fluoroquinolones, it can be continued with a regimen without moxifloxacin (BPaL regimen).

Tabel 3

The frequency distribution of drug sensitization test results in patients diagnosed with drug-resistant pulmonary tuberculosis who received BPaL/M regimen at Dr. H. Abdul Moeloek General Hospital Lampung Province (2024-2025)

DD TD notiont	Drug Sensitization Test		
DR-TB patient -	RR	MDR	Pre XDR
Number of patient	21	7	5

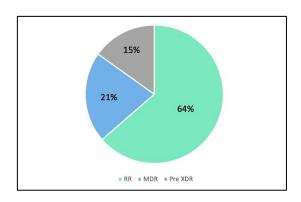


Diagram 3. The frequency distribution of drug sensitization test results in patients diagnosed with drug-resistant pulmonary tuberculosis who received BPaL/M regimen at Dr. H. Abdul

## Moeloek General Hospital Lampung Province (2024-2025)

Time to conversion of sputum MTB cultures and Success Rate

Culture conversion was an indicator whether patients are considered to have a good outcome or classified as failure cases (Conradie, 2022). In this study, there were 32 patients who were eligible to be assessed for median conversion because there are 1 patient had not converted but dropped out of treatment. There were 26 patients who showed sputum conversion results at the end of first month treatment, 5 patients who showed sputum conversion results at the end of second month treatment, and 1 patient who showed sputum conversion results at the end of third month 3 treatment (table 4).

Tabel 4
Time to conversion of sputum MTB cultures in patients diagnosed with drug-resistant pulmonary tuberculosis who received BPaL/M regimen at RSUD Dr. H. Abdul Moeloek

Conversion time	Total		
The end of 1st month	26 patient		
The end of 2 <sup>nd</sup> month	5 patient		
The end of 3 <sup>d</sup> month	1 patient		

The median sputum conversion in 32 patients diagnosed with drug-resistant pulmonary tuberculosis who received BPaL/M regimen at RSUD Dr. H. Abdul Moeloek Lampung Province was the end of first month. The treatment success of tuberculosis patients is the number of cured and fully treated tuberculosis cases among all treated and reported cases. The Ministry of Health of the Republic of Indonesia set the treatment success rate for DR-TB at 80% (Kemenkes RI 2023). The treatment success rate for patients diagnosed with drug-resistant pulmonary tuberculosis who received BPaL/M regimen at RSUD Dr. H. Abdul Moeloek Lampung Province in 2024-2025 was 83.9%.

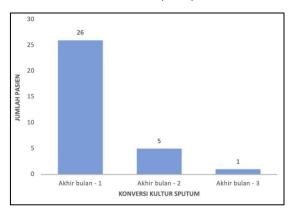


Diagram 4. Time to conversion of sputum MTB cultures in patients diagnosed with drug-resistant pulmonary tuberculosis who received BPaL/M regimen at RSUD Dr. H. Abdul Moeloek Lampung Province (2024-2025)

#### **DISCUSSION**

A short-term 6-month combination of Pretomanid. Bedaguiline. Linezolid. and Moxifloxacin (BPaLM) has been used since 2023 in Indonesia to treat patients with DR-TB without fluoroquinolone resistance. Documented cases of fluoroquinolone resistance can use the same combination but without moxifloxacin (BPaLM) (Putra, 2024). Before starting treatment and during treatment, patients need to conduct various examinations including bacteriological examinations. specifically acid-fast stain and sputum culture. Acidfast and sputum culture examinations are performed at the beginning of treatment, repeated at the end of each month of treatment and at the end of treatment (Kemenkes RI, 2023). BPaL/M combination can be given to adults and adolescents >14 years of age regardless of HIV status. The characteristics of patients with drug-resistant tuberculosis who received BPaL/M regimen at RSUD Dr. H. Abdul Moeloek Lampung Province were mostly in the productive age group, i.e. the age range of 20-44 years with a total of 15 patients or 46%.

Safety remains a critical concern. Linezolid continues to be a cornerstone of efficacy, but its hematological and neurological toxicities require structured monitoring (blood counts, neuropathy screening, dose adjustment or interruption when necessary). Recent studies emphasize the doseduration relationship of linezolid and show that lower doses (600 mg vs 1200 mg) and shorter durations can mitigate toxicity without compromising efficacy, as demonstrated in the ZeNix trial (Conradie, 2022; Sotqiu, 2012; Zhang P, 2022).

For bedaquiline, QTc prolongation is the primary concern. Pharmacometrics analyses have

shown an exposure–QT relationship, and pooled safety analyses indicate that the risk of severe arrhythmia remains low but clinically relevant, especially when combined with other QT-prolonging drugs. Best practice involves serial ECGs, electrolyte correction, and careful review of drug–drug interactions [Khan U, 2025; Pontali E, 2017; Obol MO, 2025).

There are two types of resistance in DR-TB: new resistance and secondary resistance. New resistance pattern is resistance to anti-tuberculosis drugs (ATD) in patients who have never received TB treatment before or have received OAT for less than 1 month or called primary cases. Meanwhile, resistance that occurs in patients who have received OAT treatment for more than 1 month. patients who have failed treatment, relapsed patients or dropped out of treatment is called a secondary case. The characteristics of patients with drug-resistant tuberculosis who received BPaL/M regimen at RSUD Dr. H. Abdul Moeloek Lampung Province were mostly primary resistant group with a total of 19 patients or 58%. The characteristics of the results of the drug sensitization test were most in the rifampicine resistant (RR) group with a total of 21 patients or 64%. In our study, the majority of patients had primary RR-TB. This mirrors observations that patients with RR-TB without extensive additional resistance tend to achieve faster culture conversion compared to those with broader MDR-TB resistance, highlighting the importance of early and comprehensive drug susceptibility testing to guide both eligibility and monitoring intensity (Meshesha MD, 2022).

Culture conversion was defined as at least two consecutive negative culture samples obtained with an interval of at least 7 days. Patients are considered to have a good outcome if they remain culture negative during treatment until the end of the advanced phase and are otherwise classified as treatment failure cases (Conradie, 2022). In this study, patients with drug-resistant tuberculosis at Dr. H. Abdul Moeloek General Hospital Lampung Province had a median sputum conversion at the end of month 1 treatment, with a therapeutic success rate of 83.9%. This result is exceeds the target set by the Indonesian Ministry of Health.

The results in this study are in accordance with previous studies. In a randomized clinical trial study conducted by Conradie, et al in patients using BPAL/M regimen showed the median sputum culture conversion time was 4 weeks and the treatment success rate (favorable outcome) in patients using BPAL/M regimen was 93% (Conradie, 2022). In Sangsayuh's case control study in 2024,

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the BPaL/M regimen provided rapid sputum conversion (around 4-5 weeks) and most patients achieved conversion in ≤ 8 weeks except patients with extensive lesions and large cavities who may require extended treatment duration (Sangsayunh, 2023). In a study in Indonesia by Burhan, et al the success rate of patients with BPAL/M combination was 97.6% and all patients with baseline positive cultures achieved sputum conversion in ≤ 3 months (median: 32 days) (Burhan, 2025). At the programmatic level, indirect comparisons confirm that BPaL/BPaLM regimens outperform older standards, including injectables, in both efficacy and tolerability. The shorter regimen duration, reduced hospital visits, and improved safety profile enhance patient retention and health system efficiency (Auer C, 2024).

### CONCLUSION

Based on the results of observations and research on the analysis of the success of BPaL/M regimen in drug-resistant tuberculosis at RSUD Dr. H. Abdul Moeloek Lampung Province in 2024 to 2025, it can be concluded that the characteristic profile of drug-resistant tuberculosis patients at Dr. H. Abdul Moeloek General Hospital Lampung Province in this study includes age, type of resistance, results of drug sensitivity test examination, median sputum conversion time and treatment success. The characteristics of drugresistant tuberculosis patients were mostly in the productive age group, which is the age range of 20-44 years with a total of 15 patients or 46%. Characteristics of the type of resistance were mostly in the primary resistance group with a total of 19 patients or 58%. The characteristics of the results of the drug sensitivity test were most in the rifampicine-resistant (RR) group with a total of 21 patients or 64%. The median sputum conversion in 32 patients with DR-TB who received BPaL/M regimen at Dr. H. Abdul Moeloek General Hospital Lampung Province was the end of the 1st month. with a success rate 83.9%, this number is above the target of successful treatment of DR-TB set by the Ministry of Health of the Republic of Indonesia of 80%.

### **SUGGESTION**

Future studies could compare the long-term effectiveness of the BPaL/M regimen with other treatment regimens, such as the 9-month regimen or longer durations, to assess the long-term benefits, recurrence rates, and survival rates. Further research is needed to explore the potential short-term and long-term side effects of the BPaL/M

regimen, particularly focusing on the risk of developing resistance to the included drugs.

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