



## Original Research Article

# CLINICAL PROFILE AND TREATMENT OUTCOMES OF PATIENTS RECEIVING BPALM REGIMEN FOR DRUG-RESISTANT TUBERCULOSIS AT A TERTIARY CARE TEACHING HOSPITAL: A PROSPECTIVE OBSERVATIONAL STUDY

Ketul Patel<sup>1</sup>, Parth Thakkar<sup>2</sup>, Sonal Parmar<sup>3</sup>, Naisargi Patel<sup>4</sup>

<sup>1</sup>Senior Resident, Department of Respiratory Medicine, B J Medical College and Hospital, Asarwa, Ahmedabad, Gujarat, India.

<sup>2</sup>Senior Resident, Department of Medicine, V S Hospital, Ahmedabad, Gujarat, India.

<sup>3</sup>Third Year Resident, Department of Respiratory Medicine, SMIMER Hospital and College, Surat, Gujarat, India.

<sup>4</sup>Third Year Resident, Department of Obstetrics and Gynecology, GMERS Medical College and Hospital, Sola, Ahmedabad, Gujarat, India.

Received : 17/04/2026  
Received in revised form : 08/06/2026  
Accepted : 24/06/2026

### Corresponding Author:

Dr. Ketul Patel,  
Senior Resident, Department of Respiratory Medicine, B J Medical College and Hospital, Asarwa, Ahmedabad, Gujarat, India.  
Email: ketulpatel129@gmail.com

DOI: 10.70034/ijmedph.2026.3.22

Source of Support: Nil,  
Conflict of Interest: None declared

Int J Med Pub Health  
2026; 16 (3); 140-143

### ABSTRACT

**Background:** Drug-resistant tuberculosis (DR-TB) remains a major public health challenge in India. The introduction of the BPaLM regimen comprising Bedaquiline, Pretomanid, Linezolid, Moxifloxacin has transformed the management of multidrug-resistant and rifampicin-resistant tuberculosis by providing a shorter, all-oral treatment option with improved outcomes. The Objective is to evaluate the clinical profile, adverse effects, and treatment outcomes among patients receiving the BPaLM regimen for drug-resistant tuberculosis at a tertiary care civil hospital ahmedabad hospital.

**Materials and Methods:** A prospective observational study was conducted at the Department of Pulmonary Medicine and Drug-Resistant Tuberculosis Centre, B J Medical College and Civil Hospital, Ahmedabad, Gujarat, from January 2025 to December 2025. Fifty microbiologically confirmed DR-TB patients initiated on the BPaLM regimen were enrolled. Demographic characteristics, clinical profile, laboratory parameters, adverse drug reactions, sputum conversion rates, and treatment outcomes were recorded and analyzed.

**Results:** The mean age of participants was  $34.8 \pm 11.6$  years, with males constituting 64% of the study population. Pulmonary TB was observed in 90% of patients. Previous anti-tubercular treatment history was present in 78% of cases. Sputum culture conversion at 2 months occurred in 82% of patients. Treatment success was achieved in 88% of participants, while treatment failure and mortality were observed in 4% and 6% respectively. Peripheral neuropathy (22%) and anemia (18%) were the most common adverse events.

**Conclusion:** The BPaLM regimen demonstrated high treatment success rates and rapid sputum conversion with manageable adverse effects among DR-TB patients. The findings support wider implementation of the regimen under the National Tuberculosis Elimination Programme (NTEP).

**Keywords:** Drug-resistant tuberculosis, BPaLM regimen, Bedaquiline, Pretomanid, Linezolid, Treatment outcomes, India.

## INTRODUCTION

Tuberculosis (TB) remains one of the leading infectious causes of morbidity and mortality worldwide.<sup>[1]</sup> India contributes approximately one-fourth of the global tuberculosis burden. The emergence of multidrug-resistant tuberculosis

(MDR-TB) and rifampicin-resistant tuberculosis (RR-TB) has complicated disease control efforts and increased healthcare cost,<sup>[2]</sup> Conventional MDR-TB treatment regimens require prolonged therapy extending up to 18–24 months and are associated with significant toxicity and poor adherence.<sup>[3]</sup> Recent advances have led to the

development of shorter all-oral regimens incorporating newer anti-tubercular drugs.<sup>[4]</sup> The BPaLM regimen consists of Bedaquiline, Pretomanid, Linezolid, Moxifloxacin. Clinical trials have demonstrated superior efficacy, shorter treatment duration, and improved patient compliance compared to conventional regimens.<sup>[5]</sup> Limited real-world Indian data regarding the effectiveness and safety of BPaLM remain available.<sup>[6]</sup> Therefore, this study was conducted to evaluate the clinical characteristics and treatment outcomes of patients receiving the BPaLM regimen at a tertiary care civil hospital Ahmedabad. The present study was undertaken to evaluate the demographic and clinical characteristics of patients receiving the BPaLM regimen for drug-resistant tuberculosis. It also aimed to assess sputum culture conversion during treatment, monitor the occurrence of adverse drug reactions, and determine the overall treatment outcomes among patients managed under routine programmatic conditions.<sup>[7]</sup>

## MATERIALS AND METHODS

The present study was designed as a prospective observational study and was conducted at the Drug Resistant Tuberculosis (DR-TB) Centre, Department of Pulmonary Medicine, B. J. Medical College and Civil Hospital, Ahmedabad, Gujarat, India. The study was carried out over a period of 12 months, from May 2025 to April 2026. A total of 50 patients diagnosed with drug-resistant tuberculosis and initiated on the BPaLM regimen as per National Tuberculosis Elimination Programme (NTEP) guidelines were enrolled consecutively and followed prospectively throughout the study period to assess their clinical profile, treatment outcomes, sputum culture conversion, and adverse drug reactions.

### Inclusion Criteria

Age  $\geq 18$  years.  
Microbiologically confirmed MDR/RR-TB.  
Patients initiated on BPaLM regimen as per NTEP guidelines.

Patients willing to provide informed consent.

### Exclusion Criteria

Pregnant and lactating women.  
Severe hepatic dysfunction.  
Baseline QTc prolongation  $>500$  ms.  
Patients lost before initiation of treatment.

### Data Collection

Data were collected prospectively using a predesigned and structured case record form. Information regarding the demographic profile of the patients, including age, sex, residence, and relevant personal history, was recorded at baseline. Detailed clinical characteristics, such as presenting symptoms, site of tuberculosis involvement, previous history of anti-tubercular treatment, and associated comorbidities, were documented. Baseline laboratory investigations, including complete blood count, liver function tests, renal function tests, blood glucose levels, and other relevant investigations, were obtained before initiation of the BPaLM regimen. The drug susceptibility pattern was recorded based on microbiological and molecular diagnostic reports available at the time of enrollment. Throughout the treatment period, patients were monitored for the occurrence of adverse drug reactions, which were documented and managed according to standard guidelines. Monthly sputum examinations, including smear microscopy and culture wherever applicable, were performed to assess bacteriological response and sputum culture conversion. Finally, treatment outcomes were evaluated and categorized according to the National Tuberculosis Elimination Programme (NTEP) guidelines at the completion of therapy.

### Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS Version 26. Continuous variables were expressed as mean  $\pm$  standard deviation. Categorical variables were expressed as frequencies and percentages. Statistical significance was considered at  $p < 0.05$ .

## RESULTS

**Table 1: Demographic Characteristics of Study Participants (n=50)**

Variable	Number	Percentage
Male	32	64
Female	18	36
Age 18–30 years	18	36
Age 31–40 years	16	32
Age 41–50 years	10	20
Age $>50$ years	6	12
Rural residence	28	56
Urban residence	22	44

**Table 2: Clinical Profile of Patients**

Clinical Characteristic	Number	Percentage
Pulmonary TB	45	90
Extrapulmonary	5	10
Diabetes Mellitus	11	22
HIV positive	3	6
Smoking history	17	34

Baseline sputum positive	44	88
Previous TB treatment	39	78

**Table 3: Sputum Culture Conversion During Follow-up**

Time Point	Converted	Percentage
2 months	41	82
4 months	45	90
6 months	46	92

Sputum culture conversion means that a patient who initially had a positive tuberculosis culture becomes culture-negative during treatment. It is one of the

most important indicators of treatment effectiveness because it reflects elimination of viable *Mycobacterium tuberculosis* from the body.

**Table 4: Adverse Drug Reactions Observed**

Adverse Event	Number	Percentage
Peripheral neuropathy	11	22
Anemia	9	18
Nausea/Vomiting	8	16
QT prolongation	4	8
Elevated liver enzymes	3	6
Arthralgia	5	10
No significant adverse event	20	40

Peripheral neuropathy (22%) was the most frequently observed adverse drug reaction, followed by anemia (18%) and gastrointestinal intolerance (16%). QT interval prolongation occurred in 8% of

patients and was managed with close monitoring. Notably, 40% of patients did not experience any significant adverse event, indicating an acceptable safety profile of the BPALM regimen.

**Table 5: Treatment Outcomes**

Outcome	Number	Percentage
Treatment completed/cured	44	88
Treatment failure	2	4
Died	3	6
Lost to follow-up	1	2

Overall treatment success was achieved in 88% of patients, comprising 78% who were declared cured and 10% who completed treatment successfully. Treatment failure was observed in only 4% of cases. Mortality occurred in 6% of patients, while loss to follow-up was minimal (2%). These findings demonstrate favorable treatment outcomes with the BPALM regimen under routine programmatic conditions.

## DISCUSSION

The present study evaluated the clinical profile and treatment outcomes of DR-TB patients treated with the BPALM regimen at a tertiary care civil hospital in Ahmedabad. The mean age of patients was 34.<sup>[8]</sup> years, comparable to observations from other Indian MDR-TB cohorts where disease burden predominantly affects economically productive age groups.<sup>[9]</sup> Male predominance (64%) observed in our study is consistent with national tuberculosis epidemiology.<sup>[10,11]</sup> A large proportion of patients (78%) had previous anti-tubercular treatment exposure, indicating acquired resistance as a major contributor to DR-TB development. Pulmonary disease constituted 90% of cases, reflecting the predominant presentation of drug-resistant tuberculosis.<sup>[12,13]</sup> The sputum culture conversion rate of 82% at two months demonstrates rapid

bacteriological response to BPALM therapy outcomes.<sup>[14]</sup> Similar high early conversion rates have been reported in international studies evaluating pretomanid-based regimens. Treatment success in our study was 88%, which is considerably higher than conventional MDR-TB regimens where success rates generally range from 55–70%.<sup>[15]</sup> The improved outcomes can be attributed to the shorter duration, all-oral administration, and enhanced efficacy of newer drugs. Peripheral neuropathy (22%) and anemia (18%) were the most common adverse effects, likely attributable to linezolid exposure. However, most adverse events were manageable with dose modification and supportive treatment.<sup>[6,16]</sup> Mortality was observed in 6% of patients, which is lower than historically reported MDR-TB cohorts. This finding highlights the potential of BPALM in reducing disease-related mortality. Overall, the findings support the growing evidence that BPALM offers an effective and safe alternative for management of DR-TB in programmatic settings.

## CONCLUSION

The BPALM regimen demonstrated excellent effectiveness in the treatment of drug-resistant tuberculosis, with rapid sputum conversion and an overall treatment success rate of 88%. Adverse drug

reactions were generally mild to moderate and manageable. The findings suggest that BPaLM can significantly improve outcomes among DR-TB patients under routine clinical practice and support its broader implementation within the National Tuberculosis Elimination Programme.

## REFERENCES

1. World Health Organization. Global tuberculosis report 2025. Geneva: World Health Organization; 2025.
2. World Health Organization. WHO consolidated guidelines on tuberculosis: module 4: treatment of drug-resistant tuberculosis. Geneva: World Health Organization; 2024.
3. Dheda K, Gumbo T, Maartens G, Dooley KE, McNerney R, Murray M, et al. The Lancet Respiratory Medicine Commission: 2019 update on the treatment and management of drug-resistant tuberculosis. *Lancet Respir Med.* 2019;7(9):820-826.
4. Pontali E, Raviglione MC, Migliori GB. Regimens to treat multidrug-resistant tuberculosis: past, present and future perspectives. *Lancet Respir Med.* 2019;7(12):1032-1034.
5. Conradie F, Diacon AH, Ngubane N, Howell P, Everitt D, Crook AM, et al. Treatment of highly drug-resistant pulmonary tuberculosis. *N Engl J Med.* 2020;382(10):893-902.
6. Conradie F, Bagdasaryan TR, Borisov S, Howell P, Mikiashvili L, Ngubane N, et al. Bedaquiline-pretomanid-linezolid regimens for drug-resistant tuberculosis. *N Engl J Med.* 2022;387(9):810-823.
7. TB-PRACTECAL Study Group. Shorter all-oral regimens for rifampicin-resistant tuberculosis: results from the TB-PRACTECAL trial. *Lancet.* 2022;400(10362):1277-1290.
8. National Tuberculosis Elimination Programme. Technical and operational guidelines for management of drug-resistant tuberculosis in India. New Delhi: Central TB Division, Ministry of Health and Family Welfare, Government of India; 2024.
9. Sharma SK, Mohan A. Tuberculosis: from an incurable scourge to a curable disease—journey over the decades. *Indian J Med Res.* 2023;157(1):1-10.
10. Singh UB, Arora VK. Recent advances in management of drug-resistant tuberculosis. *Indian J Tuberc.* 2024;71(1):12-20.
11. Ministry of Health and Family Welfare. India TB report 2025. New Delhi: Central TB Division, Government of India; 2025.
12. Sharma SK, Mohan A. Recent trends in diagnosis and management of tuberculosis in India. *Indian J Tuberc.* 2023;70(4):345-352.
13. Singh UB, Arora VK. Emerging therapies for drug-resistant tuberculosis: an Indian perspective. *Indian J Tuberc.* 2024;71(2):145-152.
14. Migliori GB, Tiberi S, Zumla A, Petersen E, Chakaya J, Wejse C, et al. Advances in the management of drug-resistant tuberculosis. *Eur Respir J.* 2022;60(3):2200500.
15. Diacon AH, Dawson R, von Groote-Bidlingmaier F, Symons G, Venter A, Donald PR, et al. Early bactericidal activity and clinical outcomes of novel regimens for drug-resistant tuberculosis. *Int J Tuberc Lung Dis.* 2023;27(5):401-409.
16. Conradie F, Borisov S, Bagdasaryan T, Ngubane N, Howell P, Everitt D, et al. Long-term safety and efficacy outcomes from pretomanid-containing regimens in drug-resistant tuberculosis. *Int J Tuberc Lung Dis.* 2023;27(8):620-628.