

Original Research Article

COMPARISON OF EFFICACY AND OUTCOME OF BEDAQUILINE CONTAINING VS NON-BEDAQUILINE CONTAINING SHORT COURSE REGIMEN FOR MDR TB PATIENTS IN A TERTIARY CARE CENTRE

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ABSTRACT

Background: MDR/RR-TB remains a major therapeutic challenge because of prolonged treatment, drug toxicity, microbiological persistence, and unfavourable outcomes. Bedaquiline-containing short-course regimens have emerged as an important all-oral option to improve treatment response and tolerability in drug-resistant tuberculosis. **Objectives:** This study aimed to evaluate outcomes among MDR/RR-TB patients receiving bedaquiline-containing short-course regimens, assess outcomes among patients receiving non-bedaquiline regimens, and compare the efficacy and final treatment response between both treatment groups.

Materials and Methods: This hospital-based retrospective cohort study was conducted at the PMDT site, Department of Respiratory Medicine, J.L.N. Medical College, Ajmer, from 1 January 2023 to 31 December 2023. A total of 200 registered MDR/RR-TB patients were analysed.

Results: Both groups included 100 patients each. Group B had significantly higher mean age than Group A. Clinical improvement was significantly better in the BDQ group, with complete improvement in 53 patients versus 23 patients. End-treatment sputum AFB negativity was also higher in Group A.

Conclusion: Bedaquiline-containing short-course regimen demonstrated better clinical and microbiological response than the non-bedaquiline regimen among MDR/RR-TB patients. The findings support its effectiveness in improving symptom resolution, smear conversion, and overall treatment outcome in programmatic drug-resistant TB care.

Keywords: MDR-TB, RR-TB, Bedaquiline, Short-course regimen, PMDT, Sputum conversion, Treatment outcome, Drug-resistant tuberculosis.

INTRODUCTION

Tuberculosis remains a public health problem worldwide, and drug-resistant tuberculosis has made its control difficult. Multidrug-resistant tuberculosis (MDR-TB) means tuberculosis caused by bacteria that do not respond to rifampicin and isoniazid, the two most important first-line anti-tubercular drugs. Such patients need longer, costlier, and more difficult treatment than drug-sensitive TB patients.^[1] The burden of antimicrobial resistance affects

tuberculosis care, because resistance reduces treatment options and increases the risk of treatment failure, death, and ongoing transmission. Therefore, early diagnosis, correct drug selection, and regular monitoring are very important in MDR-TB management.^[2] Short-course MDR-TB regimens were introduced to reduce treatment duration and improve adherence. Earlier studies showed that standardized shorter regimens could achieve useful treatment success in selected MDR-TB patients, but outcomes were influenced by baseline resistance,

drug tolerance, and follow-up.^[3] Programmatic experience from Karakalpakstan, Uzbekistan, showed that shorter MDR-TB regimens can be helpful, but treatment failure and resistance amplification remain concerns when the regimen does not contain enough effective drugs.^[4] Bedaquiline is a newer anti-tubercular drug that acts by inhibiting mycobacterial ATP synthase, which is essential for energy production in Mycobacterium tuberculosis. It has become important in modern MDR-TB treatment, especially in all-oral regimens.^[5] Studies from tertiary care settings have reported favorable outcomes among adults with drug-resistant TB treated with bedaquiline-containing regimens, supporting its use under careful clinical and electrocardiographic monitoring.^[6] Multicentre data from China showed that bedaquiline-containing regimens were associated with early culture conversion and acceptable safety in MDR-TB and XDR-TB patients, supporting its role in improving bacteriological response.^[7]

MATERIALS AND METHODS

Study Design: This was a hospital-based retrospective cohort study.

Study Duration: This study was carried out from 1st January 2023 to 31st December 2023 at the PMDT site, Department of Respiratory Medicine, J.L.N. Medical College and Associated Group of Hospitals, Ajmer, Rajasthan.

Sample Size: 200

Study Population: This study was conducted among all patients who were registered for BDQ-containing and non-BDQ-containing short-course regimens for the treatment of drug-resistant TB in the Department of Respiratory Medicine, Jawaharlal Nehru Medical College, Ajmer, during the specified study period.

Inclusion Criteria: Patients who were registered for bedaquiline-containing and non-bedaquiline-containing short-course regimens for the treatment of drug-resistant TB at the PMDT site were included in this study.

Exclusion Criteria

1. Patients who had refused to provide detailed history or documents were excluded.
2. Seriously ill patients who were unable to understand the questionnaires regarding this study were excluded.
3. Patients who were registered under other PMDT sites and were reporting at our site due to treatment-related issues were excluded so that results were not biased.

Methodology: After informed consent had been obtained, participants underwent history taking, clinical examination, BMI assessment, routine investigations, sputum smear testing, drug resistance evaluation, and serial chest radiographs. Clinical, microbiological, and radiological outcomes,

treatment modifications, treatment interruptions, adverse drug reactions, and final treatment status were monitored systematically to assess treatment response, safety, and overall outcomes in MDR/RR-TB patients.

Statistical Analysis: Data were recorded in Excel and summarized in a master chart. Continuous variables were analyzed using t-tests, categorical variables were analyzed using chi-square tests, and $p < 0.05$ was considered statistically significant.

RESULTS

In the present study, both groups had 100 patients each. Mean age was significantly higher in Group B than Group A (39.18 ± 14.95 vs 34.97 ± 12.46 years, $p = 0.0317$). Most patients were aged 21–50 years in both groups, with 64 patients in Group A and 80 in Group B. Male predominance was seen in both groups, 71 in Group A and 73 in Group B. Addiction was present in 54 patients in Group A and 47 in Group B. Most patients were underweight, with BMI < 18.5 kg/m² in 70 and 71 patients respectively. Comorbidity was present in 39 patients in Group A and 29 in Group B. Pulmonary TB was commonest, seen in 92 patients in Group A and 97 in Group B. Rifampicin resistance was present in 95 and 94 patients respectively, and most patients had illness duration < 5 years, 95 in Group A and 91 in Group B. Overall, both groups were comparable for most baseline variables except age.

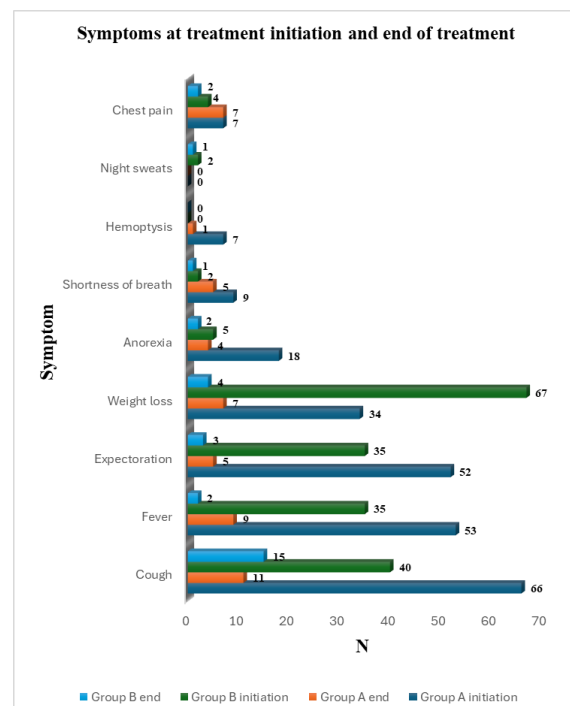


Figure 1: Symptoms at treatment initiation and end of treatment

In Figure 1 at treatment initiation, cough was the most common symptom in Group A with 66 patients, followed by fever 53, expectoration 52,

weight loss 34, anorexia 18, shortness of breath 9, hemoptysis 7 and chest pain 7, while night sweats were absent. At the end of treatment, symptoms reduced in Group A: cough 11, fever 9, expectoration 5, weight loss 7, anorexia 4, shortness of breath 5, hemoptysis 1 and chest pain 7. In Group B, weight loss was most common initially with 67 patients, followed by cough 40, fever 35,

expectoration 35, anorexia 5, chest pain 4, shortness of breath 2 and night sweats 2. At treatment end, symptoms reduced to cough 15, weight loss 4, expectoration 3, fever 2, anorexia 2, chest pain 2, shortness of breath 1 and night sweats 1. Overall, both groups showed clinical symptom improvement after treatment.

Table 1: Clinical improvement in both groups

Clinical improvement	Group A (BDQ)	Group B (Non-BDQ)
Complete improvement	53	23
Partial improvement	22	26
No improvement	10	20
Total assessed	85	69
p-value	0.00802	Statistically significant

In Table 1 clinical improvement was assessed in 85 patients in Group A and 69 patients in Group B. Complete improvement was higher in Group A with 53 patients compared to 23 patients in Group B. Partial improvement was seen in 22 patients in

Group A and 26 patients in Group B, while no improvement was seen in 10 patients in Group A and 20 patients in Group B. The difference was statistically significant ($p=0.00802$), showing better clinical improvement in the BDQ group.

Table 2: Sputum AFB status and smear conversion

Sputum AFB status	Group A (BDQ)	Group B (Non-BDQ)	p-value
Positive at treatment initiation	26	29	0.6621
Negative at treatment initiation	45	58	0.6621
Total assessed at initiation	71	87	—
Positive at end of treatment	5	12	0.006909
Negative at end of treatment	71	40	0.006909
Total assessed at end of treatment	76	52	—

In Table 2 sputum AFB was assessed at treatment initiation in 71 patients in Group A and 87 patients in Group B. At initiation, 26 patients were positive and 45 were negative in Group A, while 29 were positive and 58 were negative in Group B, with no significant difference ($p=0.6621$). At the end of treatment, 5 patients remained positive and 71 were negative in Group A, while 12 remained positive and 40 were negative in Group B. This difference was statistically significant ($p=0.006909$), showing better smear conversion in the BDQ group.

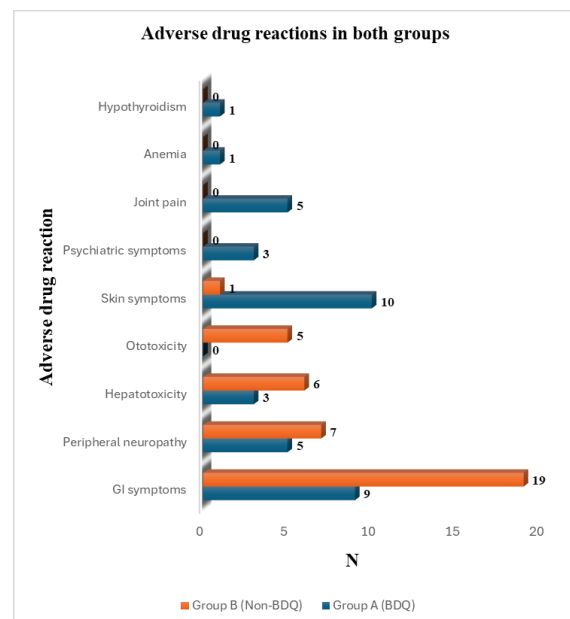


Figure 2: Adverse drug reactions in both groups

In Figure 2 adverse drug reactions differed between both groups. In Group A, the common ADRs were skin symptoms in 10 patients, GI symptoms in 9, peripheral neuropathy in 5, joint pain in 5, hepatotoxicity in 3, psychiatric symptoms in 3, anemia in 1 and hypothyroidism in 1, while ototoxicity was not seen. In Group B, GI symptoms were most common in 19 patients, followed by peripheral neuropathy in 7, hepatotoxicity in 6,

ototoxicity in 5 and skin symptoms in 1, while psychiatric symptoms, joint pain, anemia and hypothyroidism were not seen. Overall, GI

symptoms were more common in the non-BDQ group, while skin symptoms were more common in the BDQ group.

Table 3: Final treatment outcome and radiological assessment

Parameter	Group A (BDQ)	Group B (Non-BDQ)	p-value
Cured	67	31	0.00024
Death	11	23	0.00024
Lost to follow-up	10	16	0.00024
Regimen changed	8	19	0.00024
Failure	4	11	0.00024
Total patients	100	100	—
Radiological progression	17	14	0.299534
Radiological regression	62	47	0.299534
Total radiologically assessed	79	61	—

In Table 3 final outcome was better in Group A than Group B. Cure was higher in Group A with 67 patients compared to 31 in Group B, while death, lost to follow-up, regimen change and failure were lower in Group A, with 11, 10, 8 and 4 patients respectively, compared to 23, 16, 19 and 11 patients in Group B. The difference in final treatment outcome was statistically significant ($p=0.00024$). Radiological assessment was done in 79 patients in Group A and 61 in Group B, showing progression in 17 and 14 patients and regression in 62 and 47 patients respectively, which was not statistically significant ($p=0.299534$).

DISCUSSION

In the present study, both treatment arms included 100 patients each, with Group B having a significantly higher mean age than Group A (39.18 ± 14.95 vs 34.97 ± 12.46 years, $p=0.0317$), while most other baseline variables were broadly comparable. Male predominance was observed in both groups (71 vs 73), most patients were underweight with BMI <18.5 kg/m² (70 vs 71), pulmonary TB was the commonest disease form (92 vs 97), rifampicin resistance was almost universal (95 vs 94), and illness duration was <5 years in most patients (95 vs 91). Symptomatically, Group A showed marked reduction in cough from 66 to 11, fever from 53 to 9, expectoration from 52 to 5, weight loss from 34 to 7, and hemoptysis from 7 to 1; Group B also improved, with cough reducing from 40 to 15, fever from 35 to 2, expectoration from 35 to 3, and weight loss from 67 to 4. Clinical improvement was significantly better in the BDQ group, with complete improvement in 53/85 assessed patients compared with 23/69 in the non-BDQ group, while no improvement was lower in Group A than Group B (10 vs 20; $p=0.00802$). This agrees with Gao et al. (2021),^[7] who reported high culture conversion of 151/177 (85.3%) with BDQ-containing regimens, and Rehman et al. (2024),^[8] where BDQ-based regimens showed pooled treatment success of 76.9% in observational and 81.7% in experimental studies. Sinha et al. (2023),^[9] similarly supported shorter all-oral regimens for improving MDR-TB outcomes, while Gao et al.

(2024),^[10] is still a planned comparative trial and therefore provides design-level rather than outcome-level contrast. baseline sputum AFB status was comparable between both groups, with positivity at treatment initiation in 26 patients in Group A and 29 patients in Group B, while negative sputum status was seen in 45 and 58 patients, respectively; this difference was not statistically significant ($p=0.6621$). At the end of treatment, Group A showed better smear conversion, with only 5 patients remaining sputum AFB positive and 71 becoming negative, whereas Group B had 12 positive and 40 negative cases; this difference was statistically significant ($p=0.006909$), indicating superior microbiological response in the BDQ-containing regimen. This finding is clinically consistent with Gao et al. (2021),^[7] who reported high sputum culture conversion in 151/177 (85.3%) patients receiving BDQ-containing regimens, supporting the microbiological efficacy of BDQ-based treatment. Rehman et al. (2024),^[8] also reported favourable microbiological and treatment response with BDQ-based regimens, with treatment success of 76.9% in observational studies and 81.7% in experimental studies. Sinha et al. (2023),^[9] similarly emphasized that shorter all-oral regimens improve MDR-TB treatment delivery by avoiding injectable-associated toxicity and improving tolerability. In contrast, Gao et al. (2024),^[10] was a planned randomized comparison and therefore does not provide completed conversion data, but its design supports the relevance of directly comparing BDQ and non-BDQ short-course regimens.

CONCLUSION

This retrospective cohort study concluded that the bedaquiline-containing short-course regimen showed better overall efficacy and clinical outcome than the non-bedaquiline regimen among MDR/RR-TB patients managed at the PMDT site of J.L.N. Medical College, Ajmer. Both groups were broadly comparable at baseline, except for age, allowing meaningful outcome comparison. The BDQ group demonstrated superior clinical improvement, greater symptom resolution, and significantly better sputum smear conversion at the end of treatment, indicating

stronger microbiological response. The findings support the role of BDQ-containing short-course regimens as an effective treatment option for MDR/RR-TB, with improved patient response and favourable treatment outcomes.

Conflict of Interest: None.

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Ethical Approval: Obtained.

Consent: Written consent secured.

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