Section: Respiratory Medicine

Original Research Article

HEADING FOR THE STUDY: "TREATMENT INTERRUPTIONS AND SAFETY PROFILE OF BEDAQUILINE-BASED REGIMENS IN MDR/XDR TUBERCULOSIS PATIENTS: AN OBSERVATIONAL STUDY FROM MUMBAI"

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ABSTRACT

Background: Multidrug-resistant (MDR) and extensively drug-resistant (XDR) tuberculosis pose significant treatment challenges worldwide, exacerbated by adverse events associated with second-line therapies. Bedaquiline (BDQ), a novel anti-tubercular agent, has improved treatment outcomes; however, safety concerns such as QTCF prolongation necessitate close monitoring, potentially leading to treatment interruptions. This study aims to assess the frequency of treatment interruptions due to adverse events, particularly QTCF prolongation, among MDR/XDR-TB patients receiving BDQ-based longer regimens, and to evaluate patient-related factors associated with these interruptions.

Materials and Methods: An observational, descriptive study was conducted from June 2021 to March 2022 at a tertiary nodal center in Mumbai. The study included 150 MDR/XDR-TB patients initiated on BDQ-containing regimens, with data collected retrospectively and prospectively. Primary outcomes measured were incidence of treatment interruptions, while secondary analyses examined demographic and clinical variables associated with interruptions. QTCF intervals and serum magnesium levels were monitored throughout treatment.

Results: Out of 140 patients who completed follow-up, 95% completed BDQ therapy without interruption, while 5% experienced temporary or permanent treatment discontinuation due to adverse events, chiefly QTCF prolongation. Patients aged above 40 years were significantly more likely to experience treatment interruptions ($p=0.08$), with a higher risk related to comorbidities such as hypertension and COPD ($p<0.0001$). QTCF prolongation exceeding 500 ms was observed in some patients, necessitating treatment interruption or discontinuation. Hypomagnesemia was significantly associated with QTCF prolongation during therapy.

Conclusion: Bedaquiline-based regimens demonstrate a favorable safety profile with low interruption rates; however, older age, comorbidities, and electrolyte disturbances are significant predictors of adverse events leading to therapy modifications. Routine ECG and serum magnesium monitoring are essential to minimize cardiac risks and optimize treatment adherence in MDR/XDR-TB patients.

Keywords: Bedaquiline, MDR-TB, XDR-TB, Treatment Interruption, QTCF prolongation, Safety Monitoring, Tuberculosis, Adverse Events.

INTRODUCTION

Tuberculosis (TB) remains a major global health challenge, with the emergence of multidrug-resistant (MDR) and extensively drug-resistant (XDR) strains posing significant obstacles to TB control efforts. According to recent global estimates, approximately 500,000 new cases of rifampicin-resistant TB occurred in 2019, of which 78% were confirmed MDR-TB.[1]

India bears a substantial burden, accounting for an estimated 124,000 MDR/RR-TB cases (9.1 per lakh population), representing nearly 31.79% of the global MDR-TB burden.[1]

The first national anti-tuberculosis drug resistance survey (NDRS) in India revealed 28% of TB patients exhibited resistance to at least one drug, with 6.19% diagnosed with MDR-TB.[2]

Conventional MDR-TB treatment regimens have demonstrated limited success, with average treatment success rates around 49% and mortality rates approaching 50%.[3–5]

The introduction of bedaquiline (BDQ), a novel diarylquinoline antibiotic targeting mycobacterial ATP synthase, has significantly improved treatment outcomes due to its potent bactericidal and sterilizing activity.[6–8]

BDQ's inclusion in MDR-TB treatment guidelines is supported by its demonstrated efficacy in clinical trials and programmatic settings, with success rates reaching 71% in patients under BDQ conditional access programs.[9]

However, BDQ therapy is associated with safety concerns, particularly QTCF interval prolongation, which can predispose patients to potentially fatal arrhythmias such as torsade de pointes.[10]

This necessitates routine electrocardiographic (ECG) monitoring during treatment and may lead to treatment interruptions or discontinuation. Despite BDQ's critical role in MDR/XDR-TB management, data on treatment interruptions due to adverse events, especially QTCF prolongation, remain limited, particularly in the western suburban Mumbai population

This study aims to estimate the frequency of treatment interruptions associated with BDQ use, identify factors predisposing to QTCF prolongation, and characterize patient profiles associated with treatment interruptions among MDR/XDR-TB patients receiving BDQ-based longer regimens at a tertiary nodal center in Mumbai.

Aims and Objectives

Aim: To estimate the incidence of treatment interruptions among MDR/XDR-TB patients receiving BDQ-based longer regimens

Primary Objective

- To determine the number of patients requiring temporary or permanent discontinuation of BDQ due to adverse events.

Secondary Objective

- To analyze patient demographic and clinical variables associated with treatment interruptions.

MATERIALS AND METHODS

Study Design: Observational descriptive study incorporating both retrospective data collection.

Study Setting: Patients registered for MDR/XDR-TB treatment with BDQ-based longer regimens under the National Tuberculosis Elimination Programme (NTEP) from June 2021 to December 2021 at the DR-TB outpatient department (OPD) of K West Zone, suburban Mumbai, referred to the nodal center for adverse drug event management.

Location: DR-TB OPD, Nodal Center, Hinduhriday Samrat Balasaheb Thackeray Medical College and Dr. R. N. Cooper Hospital, Mumbai.

Participants: MDR/XDR-TB patients initiated on BDQ-based longer regimens attending OPD for adverse drug events.

Inclusion Criteria

- Pulmonary and extrapulmonary MDR/XDR-TB patients as per PMDT 2021 guidelines.
- Patients started on BDQ-based longer regimens.

Exclusion Criteria

- Pregnant females.
- Patients unwilling to give consent.
- Patients transferred out or lost to follow-up during treatment.

Outcome Measures

- Primary: Incidence of treatment interruptions due to BDQ-associated adverse events.
- Secondary: Patient profile variables associated with treatment interruptions.

Duration: June 2021 to March 2022.

Statistical Analysis

Data for 150 enrolled patients (140 completed follow-up) were analyzed using SPSS v22. Descriptive statistics summarized continuous variables (mean, SD) and categorical variables (frequencies, percentages).

Associations between treatment interruption status and categorical variables were assessed using chi-square tests; unpaired t-tests compared means.

Significance was set at $p < 0.05$.

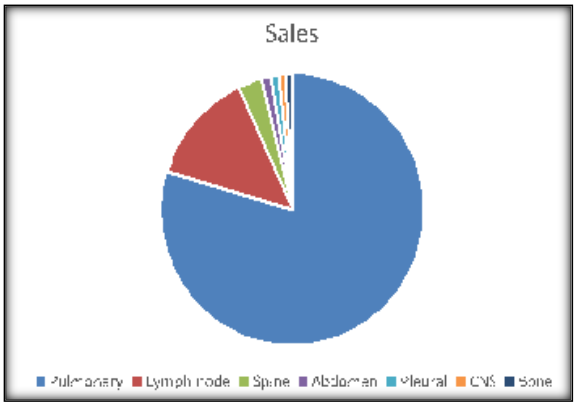
RESULTS

A total of 150 patients were enrolled; 140 completed follow-ups. Among these, 133 (95%) completed BDQ treatment without interruption, while 7 (5%) experienced treatment interruptions due to adverse events.

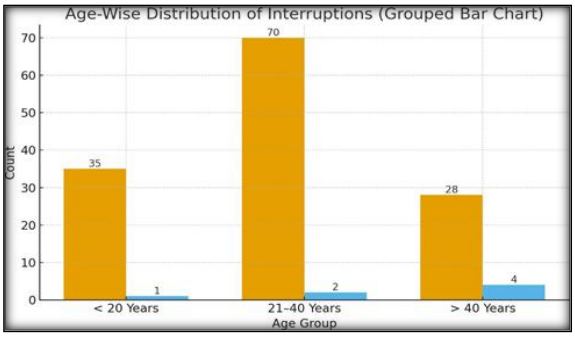
Pulmonary and Extrapulmonary involvement:

Out of 140 (available data) patients, 121 had pulmonary Tuberculosis and 19 extra-pulmonary of which 13 had Tuberculosis of lymph node, 1 patient had tuberculosis of central nervous system, 2 had tuberculosis of spine, 1 of hip bone, 1 had pleural, 1

had tuberculosis of abdomen and 1 had tuberculosis of abdomen and spine.



Frequency of Bedaquiline treatment interruptions stratified by age group.



The age >40 years group has interruption rates 4.5× higher than the younger groups.
Individuals >40 years are 5 times more likely to have interruptions.

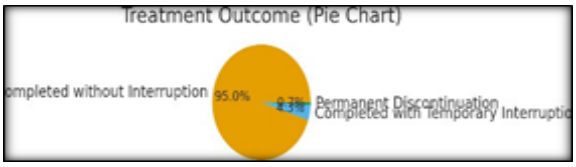


Table 1: Treatment Outcome

Category	Frequency (n)	Percentage (%)
Completed without Interruption	133	95.0%
Completed with Temporary Interruption	6	4.3%
Permanent Discontinuation	1	0.7%
Total	140	100.0%

Table 2: Age Distribution and Treatment Interruption

Variable	Total (N=140)	Completed without Interruption (n=133)	Interrupted (n=7)	P- value
Age Group (Years)				0.08
< 20	36 (25.7%)	35 (26.3%)	1 (14.3%)	
21 – 40	72 (51.4%)	70 (52.6%)	2 (28.6%)	
> 40	32 (22.9%)	28 (21.1%)	4 (57.1%)	

Table 3: Gender Distribution and Treatment Interruption

Variable	Total (N=140)	Completed without Interruption (n=133)	Interrupted (n=7)
Gender			
Male	84 (60.0%)	80 (60.2%)	4 (57.1%)
Female	56 (40.0%)	53 (39.8%)	3 (42.9%)

Chi-square = 0.025, $p \approx 0.87$ (no statistically significant association found)

Table 4: Comorbidities and Treatment Interruption

Diabetes Mellitus (DM)	2 (1.4%)	2 (1.5%)	0 (0.0%)
Hypertension (HTN)	2 (1.4%)	1 (0.8%)	1 (14.3%)
Obesity	1 (0.7%)	1 (0.8%)	0 (0.0%)
COPD	1 (0.7%)	0 (0.0%)	1 (14.3%)
Acute Renal Failure (ARF)	1 (0.7%)	0 (0.0%)	1 (14.3%)
None	133 (95.0%)	129 (97.0%)	4 (57.1%)

Chi-square = 47.80, $p < 0.0001$ (significant association)

The observed data suggest that the distribution of comorbidities differs significantly between those who completed BDQ treatment and those who stopped it. For instance, while most patients in both groups had no comorbidities, the group that stopped treatment showed a notable presence of conditions like Hypertension (HTN), Chronic Obstructive Pulmonary Disease (COPD), and Acute Renal Failure (ARF). The discrepancy between the observed and very low expected counts for these specific comorbidities (COPD, Other/ARF) in the "Stopped in-between BDQ Treatment" group largely contributes to the highly significant chi-square value, suggesting these conditions might be particularly associated with treatment discontinuation. Amongst treatment interruption age more, than 40 were 4 patients with 1 had DM 1 had COPD ON LABA+LAMA 1 had HTN 1 not having any comorbidity.

QTcF Interval Analysis

QTcF normal ranges: <450 ms (female), <470 ms (male).

Table 5: QTCF in ms amongst non interrupted and interrupted treatment groups

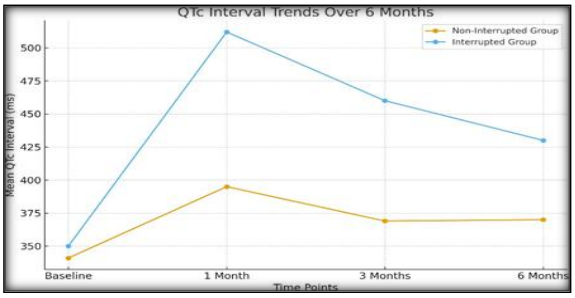
Time Point	Non-Interrupted Group Mean QTCF (ms)	Interrupted Group Mean QTCF (ms)
Baseline	341	350
Month 1	395	512
Month 3	369	460
Month 6	370	430

Patients with treatment interruption exhibited persistent QTCF prolongation, with one patient exceeding 500 ms at 6 months necessitating permanent BDQ discontinuation

Explanation and Observations

1. Baseline QTCF: Both groups presented with similar pre-treatment QTCF means (341ms vs. 350ms), well within the normal and permitted ranges, indicating no significant pre-existing QTCF prolongation.
2. QTCF During Treatment (Without Interruption Group): In the larger group (n=133) who completed treatment without BDQ interruption, the mean QTCF increased from baseline to 1 month (341ms to 395ms) but remained within the normal/permitted ranges (<450ms for females, <470ms for males). Subsequently, the mean QTCF slightly decreased at 3 months (369ms) and remained stable at 6 months (370ms). The maximum observed QTCF in this group was 440ms at 1 month, still within the safety thresholds.
3. QTCF during Treatment (With Interruption Group): The smaller group (n=6) who experienced BDQ interruption showed a dramatically different pattern. At 1 month, their QTCF was 512ms. This value significantly exceeds the normal limits (450ms for females, 470ms for males) and is indicative of severe QTCF prolongation. While their QTCF reduced to 460ms at 3 months and 430ms at 6 months, the initial elevation was substantial.

Clinical Significance of Interruption: The fact that 6 patients required BDQ interruption due to QTCF issues underscores the importance of cardiac monitoring. The case of the patient with persistently >500ms at 6 months, necessitating BDQ cessation, highlights the potential for sustained cardiac risk.



The interrupted group (blue line) shows a sharp spike >500ms at Month 1, necessitating interruption, whereas the non-interrupted group (red line) maintains a safe range <450ms throughout the course.

Details of Treatment Interruptions:

- 1 patient permanently discontinued BDQ due to severe allergic reaction.
- Temporary interruptions (n=6) were mostly due to QTCF prolongation, chest pain, or acute kidney injury. All resumed BDQ after resolution of adverse events.

The interruption group showed a significant drop in serum magnesium during BDQ interruption, correlating with QTCF prolongation

Impact of Serum Magnesium levels on Bedaquiline interruption.

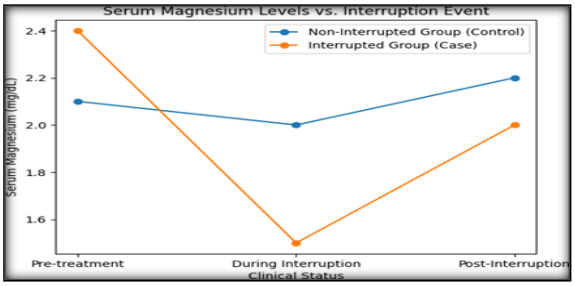


Table 5: Serum Magnesium Levels (mg/dL)

Clinical Status	Non-Interrupted Group (mg/dL)	Interrupted Group (mg/dL)
Pre-treatment	2.1	2.4
During Event (or Month 1)	2.0	1.5
Post-Correction	2.2	2.0

The interrupted group exhibited significant hypomagnesemia (mean 1.5 mg/dL) during the adverse event, which resolved upon correction and treatment pause. The figure demonstrates a clear divergence in serum magnesium trends between the interrupted (case red) and non-interrupted (control blue) groups across clinical phases. While baseline magnesium levels were comparable, the interrupted group shows a marked decline during the interruption event (mean 1.5 mg/dL), contrasting with the relatively stable levels in the control group (mean 2.0 mg/dL). This nadir coincides temporally with the interruption, supporting a clinically meaningful association between hypomagnesemia and treatment interruption. Post-correction, partial recovery of magnesium levels is observed in the interrupted

group; though values remain, lower than baseline, whereas the control group demonstrates normalization and slight improvement

DISCUSSION

This retrospective observational study investigated the incidence and possible predictors of treatment interruptions among MDR/XDR-TB patients receiving bed aquiline-based longer regimens at a tertiary health care center in Mumbai sub-urban. The observed treatment interruption rate aligns with prior literature suggesting that adverse events, particularly cardiotoxicity, are key determinants of therapy discontinuation. From previous data, Kebede et al. reported QTCF prolongation in approximately 3.2% of patients on bedaquiline, with a subset experiencing clinically significant arrhythmias necessitating drug withdrawal.[10] In our study similar low overall interruption rate (5%), predominantly driven by QTCF prolongation, without clinically significant arrhythmias which denotes and raised the safety concerns associated with BDQ therapy as documented in prior research. Notably amongst risk factors like, age >40 years, comorbidities such as hypertension, COPD, and acute renal failure significantly predisposed patients to treatment interruptions, primarily through QTCF prolongation, reaffirming the importance of vigilant cardiac monitoring. These observations are consistent with international data, yet they also highlight discrepancies worth scholarly critique.

Comparison with Global Literature: Large multicenter study (retrospective) was conducted with N=428 in 2017 to study effectiveness of BDQ based regimen where treatment interruption because of BDQ associated A.E. was 5 % which is nearby corelating with our study.[11] The global landscape of BDQ use underscores a similar safety profile, with QTCF prolongation being the most serious adverse event necessitating treatment modifications. In the pivotal Phase 2 trial conducted by Diacon et al., the rate of transient QTCF prolongation (>60 ms increase from baseline) was approximately 10-12%, with severe prolongations (>500 ms) occurring in 2-3% of patients. This is comparable to the present study, where 4.3% of patients experienced temporary interruptions due to QTCF prolongation, and one patient had sustained QTCF exceeding 500 ms, which necessitating permanent discontinuation,[12,13,14] Such findings substantiate the well-recognized cardiac safety profile of BDQ and reinforce the necessity for routine electrocardiographic (ECG) monitoring. However, unlike some large-scale randomized controlled trials (RCTs) which report higher incidences of QTCF prolongation, this study's lower interruption rate could be attributed to the retrospective nature of data collection, stricter patient selection, or perhaps improved cardiac monitoring protocols in the recent clinical setting. the WHO Solidarity Trial reported QTCF prolongation >60 ms in up to 8% of patients, with a rare occurrence of QTCF >500 ms. The discrepancy suggests variations attributable to differing participant demographics, comorbidity burdens, or ECG surveillance sensitivity.[15] The role of age as a risk factor for QTCF prolongation and treatment interruption is well documented. Harding et al.'s meta-analysis observed that older TB patients (>40 years) exhibited increased susceptibility to adverse cardiac events during BDQ therapy, which is echoed by the current findings where patients aged above 40 had five times higher odds of interruptions.[16] Similar findings appear across settings in South Africa, Russia, and China where aging populations with concurrent cardiovascular comorbidities experienced higher discontinuation rates linked to QTCF concerns. Conversely, some studies, including the controlled trial by Ng et al., found no significant age-related difference, emphasizing the importance of context-specific factors such as baseline QTCF, concomitant medications, and electrolyte disturbances and population upon which study done,[17] Comorbidities notably influenced interruptions, particularly hypertension, COPD, and renal failure showing strong associations. These findings concur with research by Lee et al., who identified that patients with existing cardiovascular or metabolic comorbidities are at increased risk of QTCF prolongation during BDQ therapy, necessitating closer monitoring and management. The observed hypomagnesemia during treatment episodes, which correlated with QTCF prolongation, mirrors existing physiological understanding that electrolyte disturbances significantly potentiate drug-induced QT prolongation. Hence, Hypomagnesemia emerged as a significant co-factor associated with QTCF prolongation and treatment interruptions. This aligns with studies indicating that electrolyte imbalances, such as hypomagnesemia and hypokalemia, predispose patients to QT prolongation and arrhythmic risk.[18] The correction of magnesium levels in our cohort appeared instrumental in allowing resumption of therapy, corroborating evidence from clinical guidelines advocating electrolyte monitoring and correction.[19] Such biochemical irregularities reinforce the concept that comprehensive management of electrolytes, particularly magnesium and potassium, is integral to safely administering BDQ.[20]

Critique of Findings in the Context of RCTs: While the current study aligns largely with previous observational cohorts and systematic reviews, it diverges from some controlled trials reporting a higher incidence of QTCF-related adverse events. For instance, the C208 study (BDQ-203) noted QTCF prolongation >500 ms in 4% of patients, with some episodes necessitating permanent discontinuation, a higher rate compared to this report. The difference may stem from the controlled environments of RCTs, where close ECG monitoring is mandatory, as opposed to real-world settings where

resource constraints and variability in adherence to ECG schedules could slightly attenuate the detection or reporting of QTCF prolongation.[21] Furthermore, some recent studies challenge the clinical significance of QTCF prolongation as a surrogate for arrhythmogenic risk. The ZeNix trial demonstrated that despite serious QTCF prolongation occurrences, the overall incidence of arrhythmias remained low; suggesting that QTCF elevation alone may not be a definitive predictor of adverse cardiac events. This raises an important question about balancing drug safety and therapeutic benefits, especially when considering the limited treatment options for MDR/XDR-TB.[22]

Limitations and Future Directions: The retrospective nature of part of this study introduces inherent biases, including reliance on routinely recorded data, potentially underestimating the true incidence of QTCF prolongation and other adverse events. In addition, the small sample size limits the generalizability of findings, and the lack of detailed pharmacogenomic data precludes analysis of individual susceptibility. Future prospective studies with larger cohorts, routine electrolyte management protocols, and advanced cardiac monitoring can better elucidate the risk factors for BDQ-associated cardiotoxicity.

In addition, the study underscores the critical importance of individualized risk assessment considering age, comorbidities, and electrolyte status before and during BDQ therapy. Pharmacovigilance systems should be strengthened to facilitate early detection of QTCF prolongation and adverse events, especially in high-risk

Groups. Integrating these findings into treatment guidelines could optimize the safety and efficacy of BDQ in diverse healthcare settings.

CONCLUSION

In summary, this study affirms the safety profile of BDQ, especially with appropriate cardiac monitoring and electrolyte management, aligning with international literature. It highlights that older age and comorbid conditions significantly predispose patients to treatment interruptions via QTCF prolongation. Hence regular cardiac monitoring, electrolyte correction, and individualized patient management are critical to ensuring continuous therapy and improved outcomes these findings contribute valuable real-world data to the existing global evidence base, emphasizing the need for careful patient selection and tailored monitoring protocols. The discrepancies between observational and randomized data accentuate the importance of context-specific evidence and underscore ongoing challenges in balancing the therapeutic benefits of BDQ against its potential risks. Future larger-scale, multicenter prospective studies are needed to validate these findings and develop standardized protocols to mitigate risks associated with bedaquiline therapy.

Ethical Consideration

HBTMC/IEC/039-22/0/RP/030/29062022/2023

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