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Original Research Article

QT interval prolongation in people treated with bedaquiline for drug-resistant tuberculosis

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ABSTRACT

Background: Bedaquiline (BDQ) is indeed recommended for treating multidrug-resistant tuberculosis (MDR-TB). However, it's essential to monitor patients receiving bedaquiline therapy closely because it has been associated with prolongation of the QTc interval. This study aimed to assess the association of bedaquiline to QT interval prolongation in DR-TB patients.
Methods: This was an observational longitudinal study conducted in the Department of Respiratory Medicine in Chest Disease Hospital, Rajshahi, from August 2020 to February 2023. A total of 44 MDR-TB patients were included in the study. Data analyses were done by using Statistical Package for Social Sciences (SPSS) version 25.0.
Results: Out of 44 patients the majority 30(68.2%) patients belonged to age >40 years with a mean age of 49.3±15.6 years, and all patients were male. All MDR patients were detected by sputum Gene-Xpert, 44 (100%), and sputum for AFB culture was done in all patients, 44 (100%). QT level and QT changes were statistically significant for baseline and 24 weeks. Only one patient died in 2 weeks of follow-up (Table 3). Changes of QT >60 ms was found in 6 (13.6%) and ≤60 ms was 38 (86.4%). Age, sex, marital status, residence, educational status, occupational status, monthly income, chief complaints, co-morbidities, and using drug-causing QT prolongation were not statistically significant (p>0.05).
Conclusions: Prolonged QT interval is in DR-TB patients who receive treatment using the bedaquiline regimen. We observed that with a moderate prolongation of QTc, there were no arrhythmias recorded and 1 death occurred due to acute MI.

Keywords: Arrhythmias, Bedaquiline, QT interval prolongation

INTRODUCTION

For years, addressing drug-resistant tuberculosis (DR-TB) has meant enduring extended courses of drugs with limited effectiveness and high toxicity, resulting in a global treatment success rate of approximately 50%.[1,2] The emergence of innovative medications like bedaquiline, delamanid, and pretomanid, alongside the repurposing of existing drugs such as clofazimine and linezolid, holds the potential to significantly enhance DR-TB treatment outcomes.[3] Since receiving approval from the Food and Drug Administration, bedaquiline (BDQ) has become a valuable addition to the limited options available for treatment of multidrug-resistant tuberculosis (MDR TB). Right from the outset, there has been enthusiasm regarding the drug's effectiveness, alongside

cautiousness regarding its safety profile.[4] Initial findings from a comparative study examining a regimen incorporating BDQ versus a standard MDR TB regimen revealed noteworthy results. Specifically, the group receiving BDQ demonstrated a significantly higher cure rate compared to the standard regimen group. Interestingly, the incidence of bad event was similar between the two groups. However, the study showed 10 deaths in the BDQ group with no clear causal pattern identified.[5] The prioritization of BDQ as a key drug in recently published guidelines underscores the importance of comprehensively understanding its safety and tolerability profile.[6,7] Precaution is emphasized due to the potential for serious adverse effects of BDQ.[8] Indeed, one of the notable side effects of Bedaquiline is its potential to prolong the QT interval, which can be observed on an electrocardiogram (ECG). The QT interval represents the duration of ventricular systole in the cardiac electrical cycle, encompassing both the depolarization and repolarization phases of the heart.[9] The ventricular cardiac action potential phase, represented by the QT interval on an ECG, where it returns to the isoelectric line. Typically, the normal QT interval ranges from 350 to 450 milliseconds (ms) in males and from 360 to 460 ms in females. Similarly, the normal corrected QT (QTc) interval falls within the same ranges for both genders. When the QT interval extends beyond 500 ms. This polymorphic ventricular tachycardia can be life-threatening, potentially leading to cardiac arrest.[10,11] Bedaquiline functions by binding to the primary energy-producing enzyme of mycobacterium tuberculosis exerting a bactericidal effect. Its action mechanism against this target helps minimize the development of cross-resistance to other anti-tuberculosis drugs (ATDs). Generally, bedaquiline is well tolerated, with only a small number of cases where treatment cessation is necessary due to poor tolerance or safety concerns.[10,11,13] In the study of Pontali et al, out of the total 1,266 patients, bedaquiline was discontinued in 44 individuals (3.5%) due to adverse effects. Specifically, only 8 patients (0.6%) had QT interval prolongation necessitating discontinuation of bedaquiline. Notably, two of these individuals were able to resume treatment after the resolution of the acute episode.[10]

METHODS

This was an observational longitudinal study conducted in the Department of Respiratory Medicine, Chest Disease Hospital, Rajshahi, from August 2020 to February 2023. A total of 44 DR-TB patients were included in the study as per inclusion and exclusion criteria.

Inclusion criteria

Patients who received treatment with Bedaquiline for drug-resistant tuberculosis, eligible patients irrespective of their background DR-TB regimen and patients who were willing to participate in the study were included.

Exclusion criteria

Patients not having a baseline ECG recorded within the 4 weeks before bedaquiline initiation, and [atients not having at least 1 follow-up ECG within the 6 months of bedaquiline treatment were excluded.

A standardized tool for data collection was made for capturing baseline characteristics, comorbidities, and treatment follow-up details, including interruptions. Electrolyte levels were measured inconsistently, limiting our ability to analyze additional torsades de pointes risk factors. Clinicians reviewed twelve-lead ECGs, recording heart rate, QT interval, and abnormalities. Random effects logistic regression assessed factors associated with QTcF >500 ms or >60 ms increase from baseline within the initial 26 weeks of bedaquiline treatment. Mixed-effects linear regression examined QTcF changes over time, accounting for within-patient correlation. Collected data were compiled and appropriate analyses were done by using computer-based software, Statistical Package for Social Sciences (SPSS) version 25.0. A p-value of less than 0.05 was considered significant. Informed written consent was taken from the subjects. Ethical clearance was taken from the ethical committee of Chest Disease Hospital, Rajshahi.

RESULTS

Out of 44 patients with drug-resistant tuberculosis, the majority 30(68.2%) patients belonged to age >40 years with a mean age of 49.3±15.6 years. All patients were male in this study. Most of the patients were married (81.8%), 27 (61.4%) patients came from rural areas, 19 (43.2%) patients completed higher school level, 25 (56.8%) patients were farmer, 26 (59.1%) patients were monthly income 10,000-20,000 Tk. Most common chief complaints were cough 42 (95.5%) followed by fever 32 (72.7%), weight loss 20 (45.5%), history of PTB 18 (40.9%), SOB 14 (31.8%) and anorexia 12 (27.3%). Regarding co-morbidities, hypertension was found in 8 (18.2%), diabetes mellitus 7 (15.9%), IHD 7 (15.96%), cardiac 6 (13.6%) and HF 1 (2.3%). Levofloxacin and clofazamine were used in 100% of patients, 7 (154.9%) used ondansetron and 3 (6.8%) used azole group (Table 1). MDR TB detected by sputum Gene-Xpert® was 44 (100%) and AFB culture was 44 (100%) (Table 2).

One case died due to acute MI at 2 weeks. QT level and QT changes were statistically significant for baseline and 24 weeks. Hypokalemia was not statistically significant in different follow-ups. Only one patient died in 2 weeks of follow-up (Table 3).

Changes of QT >60 ms was found in 6(13.6%) and ≤60 ms was 38(86.4%) (Table 4).

Age, sex, marital status, residence, educational status, occupational status, monthly income, chief complaints,

co-morbidities, and using drug-causing QT prolongation were not statistically significant (p>0.05) (Table 5).

Table 1: Baseline characteristics of the respondents (n=44).

Baseline characteristics	Frequency	Percentage
Age (years)		
≤40	14	31.8
>40	30	68.2
Mean±SD	49.3±15.6	
Sex		
Male	44	100.0
Female	0	0.0
Marital status		
Married	36	81.8
Unmarried	3	6.8
Widow	4	9.1
Divorced	1	2.3
Religion		
Muslim	42	95.5
Hindu	2	4.5
Residence		
Rural	27	61.4
Urban	17	38.6
Educational status		
None	1	2.3
Primary	7	15.9
Higher school	19	43.2
College	10	22.7
University	7	15.9
Occupational status		
Farmer	25	56.8
Businessman	8	18.2
Day labourer	4	9.1
Service	4	9.1
Rickshaw puller	1	2.3
Ex-govt service	1	2.3
Student	1	2.3
Monthly income		
<10,000 Tk	4	9.1
10,000- 20,000 Tk	26	59.1
>20,000 Tk	14	31.8
Chief complaints		
Cough	42	95.5
Fever	32	72.7
Weight loss	20	45.5
History of PTB	18	40.9
SOB	14	31.8
Anorexia	12	27.3
Hemoptysis	7	15.9
Chest pain	5	11.4
Vomiting	1	2.3
Vertigo	1	2.3
Co-morbidities		
Hypertension	8	18.2
Diabetes mellitus	7	15.9
IHD	7	15.9

Continued.

Baseline characteristics	Frequency	Percentage
Cardiac	6	13.6
HF	1	2.3
Using any drug causing QT prolongation		
Levofloxacin	44	100.0
Clofazamine	44	100.0
Ondansetron	7	15.9
Azole group	3	6.8

Table 2: MDR detected in the study patients (n=44).

MDR detected by	Frequency	Percentage
Sputum Gene-Xpert®	44	100.0
Sputum AFB culture	44	100.0

Table 3: Follow-up information of the study patients (n=44).

	Baseline	2 weeks	4 weeks	8 weeks	12 weeks	24 weeks	P value (baseline vs 24 weeks)
	Median	Median	Median	Median	Median	Median	
QT level (ms)	399.0	410.0	415.0	420.0	425.0	425.0	[a]0.001[s]
QT change (ms)	-	10.5	18.0	26.0	32.0	29.0	[a]0.001[s]
QT prolongation							
Yes	4	3	4	4	7	9	[b]0.121[ns]
No	40	41	39	39	36	34	
Hypokalemia							
Yes	2	0	0	1	0	0	[b]0.253[ns]
No	42	44	43	42	43	43	
Hypomagnesemia							
Yes	0	0	0	0	0	0	-
No	44	44	43	43	43	43	
Arrhythmia							
Yes	0	0	0	0	0	0	-
No	44	44	43	43	43	43	
Torsa des pointes							
Yes	0	0	0	0	0	0	-
No	44	44	43	43	43	43	
Need to stop BDQ due to cardiac complication							
Yes	0	0	0	0	0	0	-
No	44	44	43	43	43	43	
Death of the patient							
Yes	0	1	0	0	0	0	-
No	44	43	44	44	44	44	

One case died due to acute MI at 2 weeks, s= significant, ns= not significant, [a]P value reached from paired t-test; [b]P value reached from the chi-square test

Table 4: Change of QT of the study patients (n=44).

Change of QT	Frequency	Percentage
>60 ms	6	13.6
≤60 ms	38	86.4

We generated box and whisker plots depicting QT values over time, specifically focusing on the 24 weeks following the initiation of bedaquiline treatment. In these plots, the vertical line within each box represents the median QT value. The boundaries of the box represent the interquartile range, encompassing the 25th to 75th

percentiles of the data distribution. The whiskers extend to values within 1.5 times the interquartile range above the 75th percentile or below the 25th percentile. Any values outside this range are individually plotted as points. The number of electrocardiograms conducted at each time point is denoted in italics below the x-axis (Figure 1).

Table 5: Baseline characteristics of the study patients (n=44).

Baseline characteristics	Total	Change of QT >60 ms (n=6)		OR (95% CI)	P value
		N	%		
Age (years)					
≤40	14	1	7.1	1	1
>40	30	5	16.7	2.60 (0.24 -65.26)	0.366^{ns}
Sex					
Male	44	6	13.6	1	1
Female	0	0		-	-
Marital status					
Unmarried	3	0	0.0	1	1
Married	36	5	13.9	1.13 (0.09-29.70)	0.703^{ns}
Widow	4	1	25.0	2.33 (0.01-37.25)	0.456^{ns}
Divorced	1	0	0.0	0.01 (0.0-28.54)	0.863^{ns}
Religion					
Muslim	42	5	11.9	1	1
Hindu	2	1	50.0	0.14 (0.01-5.96)	0.257^{ns}
Residence					
Rural	27	3	11.1	1	1
Urban	17	3	17.6	1.71 (0.23-12.85)	0.425^{ns}
Educational status					
None	1	0	0.0	1	1
Primary	7	1	14.3	1.07 (0.01-13.32)	0.670^{ns}
Higher school	19	4	21.1	3.07 (0.40-28.11)	0.209^{ns}
College	10	1	10.0	0.64 (0.03-7.33)	0.584^{ns}
University	7	0	0.0	1.19 (1.04-1.38)	0.329^{ns}
Occupational status					
Farmer	25	2	8.0	1	1
Businessman	8	2	25.0	2.67 (0.26-24.51)	0.296^{ns}
Day labourer	4	1	25.0	2.33 (0.01-37.25)	0.456^{ns}
Service	4	1	25.0	2.33 (0.01-37.25)	0.456^{ns}
Rickshaw puller	1	0	0.0	0.01 (0.0-28.54)	0.863^{ns}
Ex-govt service	1	0	0.0	0.01 (0.0-28.54)	0.863^{ns}
Student	1	0	0.0	0.01 (0.0-28.54)	0.863^{ns}
Monthly income					
<10,000 Tk	4	1	25.0	2.33 (0.01-37.25)	0.456^{ns}
10,000- 20,000 Tk	26	3	11.5	0.65 (0.09-4.83)	0.475^{ns}
>20,000 Tk	14	2	14.3	1	1
Chief complaints					
Fever	32	3	9.4	0.31 (0.04-2.41)	0.193^{ns}
Cough	42	6	14.3	-	0.743^{ns}
Weight loss	20	3	15.0	1.24 (0.17-9.13)	0.574^{ns}
History of PTB	18	2	11.1	0.69 (0.08-5.27)	0.524^{ns}
SOB	14	2	14.3	1.08 (0.12-8.55)	0.633^{ns}
Anorexia	12	2	16.7	1.40 (0.15-11.37)	0.529^{ns}
Hemoptysis	7	1	14.3	1.07 (0.01-13.32)	0.670^{ns}
Chest pain	5	1	20.0	1.70 (0.01-24.20)	0.537^{ns}
Vomiting	1	0	0.0	0.01 (0.0-28.54)	0.863^{ns}
Vertigo	1	0	0.0	0.01 (0.0-28.54)	0.863^{ns}
Co-morbidities					

Continued.

Baseline characteristics	Total	Change of QT >60 ms (n=6)		OR (95% CI)	P value
		N	%		
Hypertension	8	1	12.5	0.89 (0.01-10.63)	0.703^{ns}
Diabetes mellitus	7	2	28.6	3.30 (0.32-32.30)	0.238^{ns}
IHD	7	1	14.3	1.07 (0.01-13.32)	0.670^{ns}
Cardiac	6	1	16.7	1.32 (0.00-17.41)	0.608^{ns}
HF	1	0	0.0	0.01 (0.0-28.54)	0.863^{ns}
Using any drug causing QT prolongation					
Levofloxacin	44	6	13.6	-	-
Clofazamine	44	6	13.6	-	-
Ondansetron	7	2	28.6	3.30 (0.32-32.30)	0.238^{ns}
Azole group	3	1	33.3	3.60 (0.00-71.27)	0.363^{ns}

ns= not significant, P value reached from the chi-square test

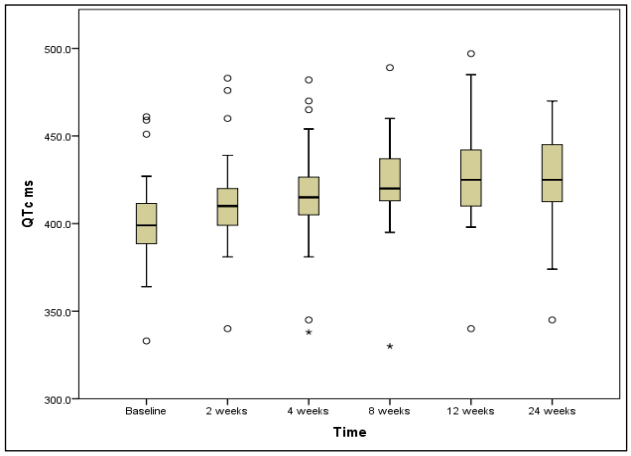

Figure 1: Box and whisker plots depicting QT values over time, specifically focusing on the 24 weeks following the initiation of bedaquiline treatment.

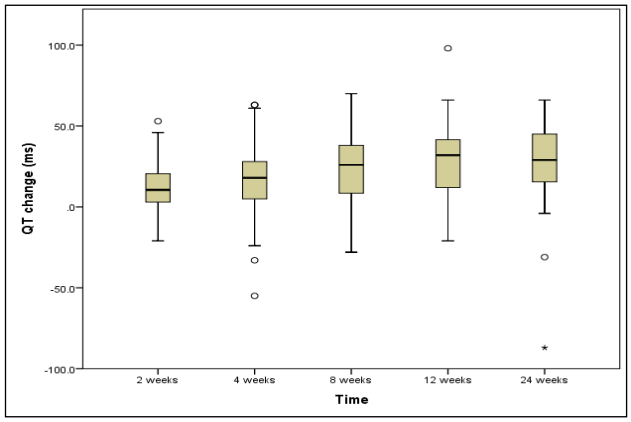

Figure 2: Box and whisker plots illustrating the change in QT from baseline over time, specifically focusing on the 24 weeks following the initiation of bedaquiline treatment

In Figure 2, the vertical line within each box represents the median change in QT from baseline. The boundaries of the box indicate the interquartile range, encompassing the 25th to 75th percentiles of the data distribution. The whiskers extend to values within 1.5 times the interquartile range above the 75th percentile or below the 25th percentile. Any values outside this range are individually plotted as points. The number of electrocardiograms conducted at each time point is denoted in italics below the x-axis.

DISCUSSION

This study observed that the majority of 30 (68.2%) patients belonged to age >40 years with a mean age of 49.3±15.6 years. In a study done by Katrak et al reported that patients on BDQ ranged in age from 15 to 75, with a median age of 38.6 years.[4] Primadana et al revealed that the mean age of 41.4±13.2 years old.[9] Darmayani et al obtained that the median age was 41 years with a range from 18 to 68 years.[15] Isralls et al also observed that, the median age was 36 (IQR 29-44) years.[3] Their study findings were consistent with the present study. In present study observed that all patients were males. In a study done by Isralls et al demonstrated that 66.2% were males.[3] Darmayani et al described that, males were 58.1% and females were 41.9%.[15] Katrak et al obtained that 16 (43%) were female.[4] Primadana et al also found males predominance (58.7%) compared to females (41.3%).[9] The above-mentioned study's findings were inconsistent, due to all patients were male in this study. Regarding co-morbidities, hypertension was found in 8 (18.2%), diabetes mellitus 7 (15.9%), IHD 7 (15.96%), cardiac 6 (13.6%) and HF 1 (2.3%). A study done by Darmayani et al reported that hypertension was found in 2 patients, DM in 31 patients, heart disease in 1 patient.[15] Isralls et al observed hypertension was 7.6% of patients, and diabetes in 4.5% of patients, which was supported by the present study.[3] This study observed that Levofloxacin and Clofazamine were used in 100% of patients, 7 (154.9%) used ondansetron, and 3 (6.8%) used azole group. Darmayani et al documented that levofloxacin was found in 20 patients, and moxifloxacin in 3 patients.[15] This present study observed that QT level and QT changes were statistically significant for baseline and 24 weeks. Hypokalemia was not statistically significant in different follow. Only one patient died in 2 weeks of follow-up. According to Katrak et al, among individuals with an

available baseline ECG, 22 out of 23 (95.7%) displayed a normal baseline QTc, with only one patient receiving BDQ exhibiting a baseline QTc of 475 ms.[4] The median QTc at baseline stood at 428 ms, with subsequent median values at week 2, 438 ms; week 4, 432 ms; week 8, 426 ms; week 12, 424 ms; and week 24, 388 ms. The median peak QTc interval was 455 ms, accompanied by a median increase in QTc from baseline to peak of 23 ms, and a median time to peak of 57 days. Primadana et al found that the mean QT interval prolongation with the bedaquiline regimen was 13.3 ms at one month and 14.6 ms at six months of therapy, comparing with baseline.[9] Although the mean QT interval at six months was longer than at one month, this disparity lacked statistical significance. These findings parallel those of Isralls et al, whose study involving 420 patients revealed that the mean baseline QT interval was 406.4 ms.[3] After three months of treatment, it prolonged to 430.5 ms, and after six months, it reached 434.0 ms Darmayani et al also observed during BDQ treatment, seven subjects (6.7%) died.[15] The above-mentioned studies finding were almost consistent with this study. This current study observed that changes of QT >60 ms were found in 6(13.6%) and ≤60 ms was 38(86.4%). Darmayani et al described that, 38 subjects (36.2%) were detected with QTc >60 ms.[15] Isralls et al described that, 110 patients (26.2%) had a change of >60 ms from baseline (253 episodes).[3] Their study findings were consistent with the present study. Primadana et al conducted a study indicating that in individuals aged over 45 years old, the QT interval after one month of therapy was longer compared to after six months of therapy.[15] This difference was influenced by the doses of bedaquiline administered. Initially, a higher dose of 400mg once a day was given for the first two weeks of treatment, followed by 200mg three times a day for 22 weeks. This dosing regimen resulted in alternating QT intervals due to the decline in bedaquiline M2 levels. A higher dose led to a longer prolongation of the QT interval.[16]

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community. This was the main limitation of study.

CONCLUSION

QT interval prolongation is observed in DR-TB patients who receive treatment using the Bedaquiline regimen. However, no arrhythmias were recorded, further supporting data suggesting that bedaquiline is safe under programmatic conditions.

Recommendations

Multicenter studies with a bigger sample and an extended study duration are recommended. Further cohort studies are required to evaluate the cumulative effect of QT prolongation due to the long elimination half-life of BDQ. Patients should be followed up with after the end of their treatment. This study could not assess this, as there was no ECG record after BDQ use (after six months). Furthermore, BDQ concentration was not measured.

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Ethical approval: The study was approved by the Institutional Ethics Committee of Chest Disease Hospital, Rajshahi

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