

QT changes of unforeseen implications and bedaquiline: an observational study

Sandip Mukhopadhyay¹, Samya Dutta², and Rupam Ta²

¹Burdwan Medical College

²Affiliation not available

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Abstract

Background: Bedaquiline (BDQ) is a relatively new agent for multidrug (MDR) and extremely drug resistant (XDR) TB. It is important to look for cardiac safety and the bizarre adverse reactions after initiation of the drugs from the real world studies. Methods: An observational study was conducted on the institutionalized MDR and XDR patients under the conditional access program of BDQ in India. Daily ECG, adverse events and change in laboratory values for first two weeks were recorded with mortality and serious adverse events till first three months of initiation of BDQ containing regimen. Results: Among the total of 49 patients, nausea (n=33) was the most reported side effect. Though a mean rise of QTcF (12%) was noted after 14 days, individually, both prolongations (QTcF >440 ms) and shortening (from baseline values) of QTcF were noted in 95.92% (n=47) and 89.8% (n=44) patients. Three distinct QT patterns noted in ECG were, a) initial rise then fall (n=8), b) initial fall then rise (n=9) and c) rise followed by further rise (32). There was no serious adverse event leading to drug withdrawal or mortality in the first three months. Conclusions: Prolongation of QTcF occurs in alarming numbers during first two weeks of BDQ therapy as well as shortened QT. However, BDQ was otherwise tolerated well by the real world MDR & XDR-TB patients in short term. Intensive ECG and clinical monitoring is recommended to detect possible serious implications of such ECG changes in the long term.

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