PHARMACOKINETIC STUDY OF BEDAQUILINE AMONG INDIAN MDR-TB PATIENTS IN CLINICAL SETTINGS

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January 24, 2021

Abstract

Bedaquiline, a novel drug was approved for the treatment of multi-drug resistance tuberculosis (MDR-TB) by the US FDA in 2012. It is majorly caused because of the transmission of multi-resistant strain from a diseased person to a healthy individual and by genetic factors. Safety, efficacy, and bactericidal activity of Bedaquiline were reported in various studies, but the pharmacokinetic analysis of Bedaquiline in clinical settings was unclear. This study serves as evidence for the physicians regarding the pharmacokinetic data and managing drug therapy and for better patient outcome in routine clinical practice. This study is conducted in a total of 58 patients with newly diagnosed, smear-positive, MDR-TB patients who received Bedaquiline as per RNTCP guidelines. Plasma samples were collected after the Bedaquiline administration. The patient samples were analyzed. The pharmacokinetic data were drawn by using software kinetic-2000, version 5.03.The observed Cmax was 2523.08 ng/mL, Tmax was reached at 4 hrs, AUC(0-24) was 21727.1 ng *hr/mL, AUMC (0-24) was 222953.8 ng *hr2/mL. Whereas the half-life of the drug was found at 7 .02 hrs and mean residence time (MRT) was found to be 10.25 hrs respectively. The data was even on the 14th day of therapy. The Cmax is shown to be 5937.1ng/mL reaching the Cmax at about 5 hours. While the AUC(0-24) was found to be 65780 ng *hr/mL. Conclusively, pharmacokinetic parameters were evaluated and found to be within the desired limits with minimal changes. This method can be further used for the quantification of Bedaquiline in routine clinical practice.

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