Modifications on the BPaL regimen in under Operational research in the Philippines

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Title

Scientific Research Abstract Text

Background: In 2020, WHO recommended 6 months of standardized regimen consisting of bedaquiline, pretomanid and linezolid (BPaL $_{1200\ mg/day}$) under operational research (OR) for eligible rifampicin-resistant TB patients. In 2021, the BPaL OR protocol and Clinical Guide were developed under LIFT-TB. In case of toxicity, modifications are allowed including a) BPaL regimen interruption during the first 4 weeks of treatment for ≤14 days, and ≤35 days thereafter, with missed doses made up at end of treatment; b) Linezolid modification through dose reduction, interruption or discontinuation after 4 weeks of Linezolid 1200 mg/day, or after 9 weeks of 600 mg/day.
Design/Methods: This abstract describes the occurrence of protocol modifications on the BPaL(1200 mg/d) regimen under OR in the Philippines from June 2021- December 2022. Data were obtained from REDCap and OR databases.
Results: Among 58 patients who finished 6 months of treatment, BPaL interruption occurred in 8 (14%) patients due to peripheral neuropathy (3), myelosuppression (2), QT prolongation (1), hepatotoxicity (1) and surgery of unrelated cause (1). Interruption duration was 2-22 days at various treatment stages. Majority of AEs were resolved with no reappearance upon re-introduction of the BPaL regimen.

Among the 58 patients, Linezolid modifications occurred in 22 (38%) patients in 30 episodes: temporary interruption occurred in 21 (70%), dose reduction in 7 (23%), permanent discontinuation in 2 (7%) with AEs partially or completely resolved. AEs included peripheral neuropathy in 13, myelosuppression in 11, optic neuritis in 1, and undocumented in 1. Treatment success remained exceptionally high at 97% despite the modifications.
Conclusions: WHO guidelines allow reasonable modifications to the 6-month BPaL-based regimens to ensure drug safety with no compromise to efficacy. Strengthening active drug safety monitoring and management is crucial in the introduction of the new regimens to detect and strategically manage adverse events in a timely manner.

Summary

Summary: WHO guidelines allow reasonable modifications to 6-month BPaL-based regimens ensuring drug safety with no compromise to efficacy. This abstract narrates the experience in the Philippine BPaL OR where regimen modifications occurred among patients who have finished 6 months of treatment and the treatment success despite the changes.

Other Fields
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