Adverse events on patients taking the BPaL regimen under Operational Research conditions in the Philippines

M. Trono,[1] M. Quelapio,[2] I. Flores,[3] R. Cervas,[4] V. Mirtskhulava,[5] S. Foraida,[6] C. Cabalitan,[4] J. Carpin,[4] S. Jung,[7] D. Omanito,[8] C. Salido,[8]
[1]Tropical Disease Foundation, Inc., LIFT-TB Philippines Project, Makati City, Philippines, [2]KNCV/TB Alliance, LIFT-TB Project, Metro Manila, Philippines, [3]Jose B. Lingad Medical Center, Satellite treatment center, City of San Fernando, Philippines, [4]Lung Center of the Philippines, Program Management Office, Quezon City, Philippines, [5]KNCV, LIFT-TB Project, The Hague, Netherlands, [6]TB Alliance, Medical Affairs, New York City, United States of America, [7]International TB Research Center, LIFT-TB Project, Seoul, Republic of Korea, [8]Department of Health, Disease Prevention and Control Bureau, Manila City, Philippines

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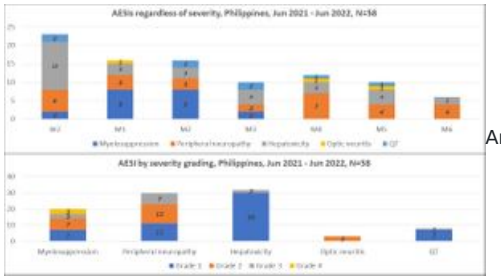
Category: Scientific research
Prefered presentation type: Oral abstract presentation

Track selection
Track: B3: Clinical trials and operational research for new treatments for TB (for adults and children)

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 (RR-TB) patients. Safety objectives according to the OR protocol included determination of serious adverse events (SAEs) and adverse events of special interest (AEs), namely peripheral neuropathy, myelosuppression, optic neuritis, hepatotoxicity and QT prolongation. OR site staff underwent training on active TB drug safety monitoring and management (aDSM) including the identification, and clinical management of adverse events based on severity grading. The TB Medical Advisory Committees provided clinical advice to the OR sites and the Research team did regular monitoring.
Design/Methods: This abstract describes the occurrence of adverse events in patients enrolled on the BPaL regimen with Linezolid initiated at 1200 mg/day. Data were obtained from REDCap and OR databases.
Results: 

Among 58 patients who finished 6 months of treatment, serious adverse events occurred in 7 (12%) patients: death (1); life threatening situation (2), hospitalization (2), and persistent or significant disability (2). There were 93 episodes of AEs of special interest among the 58 patients: hepatotoxicity (32), peripheral neuropathy (30), myelosuppression (20) and QT prolongation (8) and optic neuritis (3). Despite the high number of AEs, majority were mild (59%) with no intervention needed, 23% moderate, 14% severe and 3% life-threatening. Majority resolved with Lzd modification.
Conclusions: Although AEs occurred quite frequently in patients on BPaL, majority of these AEs were mild and required no intervention. Moreover, this cohort received 1200 mg/day of Linezolid. With reduced Linezolid dose to 600 mg/day per WHO recommendation, lesser AEs are anticipated during programmatic implementation. Nonetheless, aDSM remains a crucial component in the introduction of new regimens with capacity building needed for AE identification, severity grading and appropriate and timely clinical management.

Summary

Summary: Most adverse events (AE) in BPaL are those known to be Linezolid-associated. This abstract describes the cohort of 58 patients in the Philippines who completed 6 months of treatment under operational research initiated with Linezolid 1200 mg/day, and the occurrence of AEs and their severity.

Other Fields
Country of research: Philippines
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