

Cutaneous lesions of patients treated with BPAL in the Philippines under Operational research

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Type selection

Category: Scientific research

Preferred 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 BPAL consisting of bedaquiline, pretomanid and linezolid under operational research (OR) for fluoroquinolone-resistant, intolerant and non-responsive rifampicin-resistant TB patients. Adverse events (AE) of special interest of BPAL are focused on neuropathies and myelosuppression which are associated with Linezolid. Other AEs may occur in the clinical setting noted during active drug safety monitoring and management (aDSM).

Design/Methods: This is a descriptive study of patients on BPAL in the Philippines that manifested with cutaneous lesions.

Results: The BPAL OR in the Philippines enrolled 103 patients from June 2021-December 2022 of whom at least 24 (23%) were observed to have cutaneous lesions: 63% female; 54% aged 20-29 years (range: 20-52 years). While 58% did not have any comorbidity, 25% had diabetes, 13% had prior hypersensitivity, and 13% were PLHIV. Lesions were mostly acne-like, 72% occurring on the face, 17% on the chest, 13% in the underarms; few under the breasts, abdomen, lower extremities, scalp and neck. Others manifested as finer raised lesions; others as flat areas of erythema or hyperpigmentation, or as scaly lesions. Two patients had hair loss and psoriasis. The onset occurred within the first month of BPAL initiation in 92%, and 8% within the second month. No interventions were done in 46%; Cetirizine was taken in 46%; two patients consulted with specialists. Partial or complete disappearance of the lesions was observed in 96% during the treatment course; 4% were undocumented.

Conclusions: aDSM remains crucial as new drugs and regimens are being introduced more widely. Although non-life-threatening, cutaneous manifestations occurred in a quarter of patients and, if left unaddressed, can cause unnecessary anxiety, possibly leading to loss to follow-up. It was, however, observed that these AEs tend to be mild and reversible, reassuring both patients and health providers of the safety of the regimen on the skin.

Summary

Summary: The WHO recommended 6 months of bedaquiline, pretomanid and linezolid for eligible rifampicin-resistant TB patients in 2020. Known adverse events are focused on neuropathies and myelosuppression. The BPAL OR in the Philippines encountered cutaneous lesions in a proportion of its cohort of patients with different presentations.

Other Fields

Country of research: Philippines

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