Title:

Delamanid for rifampicin-resistant tuberculosis: an observational cohort study from Khayelitsha, South Africa

Authors:

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Background

Delamanid (DLM) is efficacious in the treatment of rifampicin-resistant tuberculosis (RR-TB) and was recommended by the World Health Organization in 2014. Experience with DLM outside of clinical trials has been limited, particularly among patients with HIV. We aim to describe early efficacy and QT safety profiles from a programmatic setting in Khayelitsha, South Africa.

Design/Methods:

This was an observational cohort of patients who had DLM included in their second-line treatment regimen between November 2015-March 2017. Interim treatment outcomes, sputum culture status, and QTc values at 6-months were determined.

Results:

Overall, 73 patients initiated RR-TB treatment containing DLM; 41 (56.2%) were male, 68 (93.2%) were >19 years, 75% were HIV-positive, and 48% and 36% had multi-drug resistant tuberculosis (MDR-TB) and MDR-TB with second-line resistance, respectively. Of them, 44% (32/73) had <6-months of follow-up. Interim outcomes 6-months after DLM initiation were available for 56% (41/73) patients; 66% (27/41) were still on treatment and culture negative, 2% (1/41) was still on treatment and culture positive, 10% (4/41) were still on treatment with no available culture data, 7% (3/41) died, 7% (3/41) were transferred, 5% (2/41) were lost-to-follow-up, and 2% (1/41) was cured. Among, the 32 patients still on RR-TB treatment by 6-months, 3% (1/32) had DLM replaced by BDQ at 5 weeks when admitted to an outside hospital. Only 15% (5/32) patients experienced a temporary QTcB value greater than 500ms; none of these patients required permanent withdrawal of DLM.

Conclusions:
Early treatment outcomes using DLM in a programmatic, primary care setting with high HIV prevalence are extremely promising. Access to DLM should be urgently expanded to improve treatment options for RR-TB patients.