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Background

In 2018, the reported tuberculosis cases in Malaysia were 25,173 with an estimated incidence rate of 92 cases per 100,000 populations. Globally, 7.1 million people with TB were diagnosed and 1.4 million died of TB in 2019. In 2018, the United Nations set a target to diagnose and treat 40 million people with TB including 3.5 million children and 1.5 million of drug-resistant patients in a five-year period (2018-2022). Since then, the TB treatment coverage increased from 69% in 2018 to 71% in 2019.

On the other hand, drug-resistant among TB patients keep increasing. A systematic review (SR) in 2016 stated that generally, first-line treatment for drug-susceptible TB was effective but inadequate exposure to anti-TB may constitute one of the factors underlying suboptimal treatment response. This suggested that ensuring appropriate serum concentrations of anti-TB drugs in patients on treatment for active TB may improve treatment outcomes. Measurement of blood drug concentrations may also be referred as therapeutic drug monitoring.

Therapeutic drug monitoring (TDM) is an individualisation of drug dosage by maintaining plasma or blood drug concentrations within a targeted therapeutic range or window. The goal of TDM is to individualise therapeutic regimens for optimal patient benefit.

This technology review was requested by the Head of Sector of Tuberculosis and Leprosy Control, Disease Control Division, Ministry of Health based on issues raised by Respiratory Physician and Paediatric Specialist.

Objective

The objective of this technology review was to assess the efficacy/effectiveness, safety and cost-effectiveness of therapeutic drug monitoring (TDM) in tuberculosis treatment.

Methods

Literature search was conducted with help from an Information Specialist who searched for published articles pertaining to TDM in TB treatment. The following electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-Process & Other Non-Indexed Citations and Ovid MEDLINE® 1946 to 10th August 2021. Parallel searches were run in PubMed, US FDA, CADTH, and INAHTA database. No limits were applied to the search. Any additional articles were identified from reviewing the references of retrieved articles. The last search was performed on 12th August 2021.

Results and conclusion:

In patients on first line anti-TB treatment, concentration level of the anti-TB drugs was not associated with patient outcome. However, for second line anti-TB drugs, TDM was used to ensure therapeutic drug level to avoid toxicity. In term of safety, TDM was used for detection of any over dosage or low dose anti-tuberculosis among patients with sign and symptom of toxicity and unresponsive towards treatment. There also study reported that, poor compliance of anti-TB drug in sputum non-conversion group compared to sputum conversion group. Currently, no cost-effectiveness study retrieved related to TDM for anti-TB drug.

