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Title: Adverse drug reactions and outcomes of tuberculosis treatment using fixed-dose combination (FDC) regimen

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Body: Background 4-drugs Fixed-dose combinations (4FDCs) for treatment of tuberculosis (TB) have been encouraged to prevent the emergence of drug resistance; increase compliance and tolerance to treatment. However, there are limited data regarding adverse drug events (ADE) with this therapeutic regimen. Objective: To assess the ADE and outcomes of 4FDCs for the treatment of tuberculosis. Methods: Clinical and laboratories information were collected from medical records of 70 outpatients treated with 4FDCs including a tablet doses: rifampicin 150mg/isoniazida75mg/ pirazinamida 400mg/ ethambutol 275, as recommended by World Health Organization and adopted by Brazilian guidelines at 2010. Results: The results showed that 17% were human immunodeficiency virus (HIV) infected.The pulmonary form was predominant (76%). ADE occurred in 86%, including 29 different types of events. The most frequent were hiperuricemia (63%) followed by nausea and epigastralgia in 22% and pruridus in 11%.The majority of patients (66%), presented more than one event. Around the 15th day of treatment, laboratorial abnormalities (hepatotoxicity and hiperuricemia) related with drugs were detected in blood samples in 71% of patients. The change in therapeutic regimen due to serious ADE was required in just 2 patients (due to liver toxicity and hiperuricemia). Other outcomes were bacterial resistances (2) defaults (14) and cures (52). Conclusions: The ADE was frequent with The 4FDCs regimen TB treatment, but changes in therapeutic regimens were necessary in less than 3% of patients. These findings support, at least, the need of clinical surveillance as it may avoid unnecessary changes in therapeutic regimens.