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Title: Frequency, severity and risk factors of drug-induced liver injury during treatment of new tuberculosis patients

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Body: Background Drug-induced liver injury (DILI) is one of the most serious problems complicating anti-tuberculosis (anti-TB) treatment. The aim of the study was to assess the incidence, severity of and risk factors for DILI among new TB patients. Methods 200 HIV-uninfected new pulmonary TB patients admitted to Research and Clinical Center for TB control 2009 to 2011 were monitored for clinical and laboratory signs of DILI during the intensive phase of treatment. The median age was 28.0 (IQR 22-44) yrs, 93 were female, 108 were smear-positive, 172 received only first-line anti-TB drugs. The relationship between independent covariates (demographic and clinical data of patients) with frequency of DILI was analysed using multivariate logistic regression. Results The frequency of DILI (serum alanine aminotransferase (ALT) > 3 x the upper limit of normal [ULN]) was 32.5% (65/200 patients). Severe hepatotoxicity (ALT > 10 x ULN) occurred in 10.5% (21/200). 42 patients (21%) experienced hepatic adaptation (asymptomatic, transient elevation of ALT < 3 x ULN). The type of DILI was hepatocellular in 90.8%, cholestatic in 6.2% and mixed in 3.1%. The relationship between drug and DILI was definitive in 60% (39/65) cases. Female sex (OR = 2.11, 95%CI: 1.08-4.12) and a history of drug/food allergy (OR = 2.94, 95%CI: 1.33-6.49) were identified as risk factors for developing a DILI. Conclusion Drug-induced liver injury is frequent complication of anti-TB treatment among new TB cases associated with female sex and a history of drug/food allergy, but not with alcohol abuse and concomitant diseases.