HEPATOTOXICITY IN PATIENTS CO-INFECTED WITH TUBERCULOSIS AND HIV-1 WHILE RECEIVING NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR-BASED ANTIRETROVIRAL THERAPY AND RIFAMPICIN-CONTAINING ANTI-TUBERCULOSIS REGIMEN

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Abstract. To evaluate the rate of and risk factors for hepatotoxicity in tuberculosis (TB) and human immunodeficiency virus type 1 (HIV-1) co-infected patients while receiving non-nucleoside reverse transcriptase inhibitor (NNRTI)-based antiretroviral therapy (ART) and a rifampicin (RMP)-containing anti-TB regimen. We analyzed data from the N2R study which was an open label, randomized, comparative trial comparing treatment outcomes between 71 TB/HIV-1 co-infected patients receiving efavirenz (EFV)-based and nevirapine (NVP)-based ART; all of whom were receiving RMP-containing anti-TB treatment. Demographic data, liver function test, CD4 cell count, plasma HIV-1 RNA, hepatitis B surface antigen and anti-hepatitis C virus antibody were collected before initiating ART (week 0). Liver enzymes and total bilirubin levels were monitored at 6 weeks, 12 weeks and 24 weeks after ART initiation. All patients were followed until TB therapy was completed. Of 142 patients, 8 patients were excluded. Among the remaining 134 patients, the mean ± SD age was 36.8 ± 8.6 years and 67.2% were male. Severe hepatotoxicity (grade 3 or 4) developed in 4 patients (2.9%); 3 patients (4.6%) in the NVP group and 1 patient (1.4%) in the EFV group. Severe hyperbilirubinemia (grade 3or 4) occurred in 7 patients (5.2%); 5 patients (7.7%) in the NVP group and 2 patients (2.9%) in the EFV group. Grade 1 or 2 hepatotoxicity occurred in 34 patients (31.4%). Hepatitis C virus co-infection (adjusted OR 3.03; 95%CI 1.26-7.29) was an independent risk factor associated with grade 1-4 hepatotoxicity (p=0.013). Monitoring of hepatotoxicity should be considered in TB/HIV-1 co-infected patients who are infected with HCV and receiving NVP.

Keywords: TB-HIV-1 co-infected patients, hepatotoxicity, NNRTI-based ART, RMP

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