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Abstract (poster session)
Time to initiation of antiretroviral therapy between 4 weeks and 12 weeks of tuberculosis treatment in HIV-1 infected patients. Results from the TIME Study

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Background: Optimal timing for initiation of antiretroviral therapy (ART) among HIV-1 infected patients with tuberculosis (TB) is limited in the setting of early ART at CD4 count of <350 cells/mm3 in the middle income countries. Methods: Thai HIV/TB co-infected patients who had CD4 count of <350 cells/mm3 and diagnosed TB were randomized to initiate a once daily regimen of tenofovir/lamivudine/efavirenz at 4 weeks (group A) versus 12 weeks (group B) of TB treatment between 2009-2011. The primary endpoints were all-cause mortality and hospitalization according to an intent-to-treat analysis. Results: Of 156 patients, 79 were in group A and 77 patients were in group B. Overall mean±SD age was 38±9 years; median (IQR) CD4 was 43 (47-106) cells/mm3; and median (IQR) HIV-1 RNA was 5.8 (5.4-6.3) log copies/mL. Eighty-three (53%) patients were diagnosed extra-pulmonary or disseminated TB. Eleven (7%) mortalities occurred in a totaling of 137 patient-years of follow-up. Seven percent (6/79, 8.76 per 100 patient-years) mortalities were in group A and 6% (5/77, 7.25 per 100 person-years) mortalities were in group B (OR=0.845, 95%CI=0.247-2.893, P>0.99). The same trends were found in the subgroup of patients with baseline CD4 count < 100 cells/mm3 (9% vs. 13%, RR=1.591, 95%CI=0.396-6.397, P=0.725) and <50 cells/mm3 (8% vs. 10%, RR=1.239, 95%CI=0.338-4.542, P=0.753). Twenty-eight (35%) patients in group A and 25 (32%) patients in group B were hospitalized (OR=1.142, 95%CI=0.588-2.217, P=0.737). Grade 2-4 adverse events related to ART and TB treatment were 39% (31/79) in group A and 34% (26/77) in group B (OR=1.267, 95%CI=0.659-2.435, P=0.509). In multivariate analysis adjusting for timing to initiating ART, 'low albumin' (OR=3.717, 95%CI=1.529-9.009, P=0.004) and 'low baseline CD4 count' (OR=1.014, 95%CI=0.999-1.029, P=0.061) were the independent predictors of all-cause mortality. Immune reconstitution inflammatory syndrome was more frequent in group A with an incidence of 8.86 vs. 5.02 per 100 person-months in group B over the first 6 months of ART (P=0.069). Conclusions: In this study which conducted in a middle income country with early ART at CD4 count of <350 cells/mm3, survival advantage associated with very early initiating ART in HIV-infected patients with active TB was not found in any CD4 stratum. However, patients with low albumin and low baseline CD4 count were associated with higher risk of death.