

ABSTRACT

Background: In 2011, Kenyan HIV treatment guidelines changed from initiating ART at a CD4 of ≤ 200 to ≤ 350 cells/uL. We compared 6-month mortality in 2 research cohorts, one enrolled before and one after the 2011 ART initiation guidelines changed. We hypothesized that following the new guidelines, 6-month post-ART mortality would be lower.

Methods: HIV seropositive adults were enrolled in 2 clinical trials at the Coptic Hope Center, Kenya, in 2006 (drug adherence intervention) and 2013 (drug resistance testing intervention, ongoing). In both trials, participants were enrolled prior to ART initiation and started ART following enrollment. Missed visits were investigated to determine if the participant had died using standardized procedures. Linear regression was used to compare mean baseline CD4 count and Cox proportional hazards regression was used to compare 6-month mortality between the two studies. Subjects who enrolled after January 31 2014 were omitted from the analysis.

Results: There were 362 and 379 participants in 2006 and 2013 cohorts with at least 6 months of follow-up time. 25 participants in 2013 and none from 2006 were missing a baseline CD4 count. The proportion of female participants in each cohort was 66% and 37%, in 2006 and 2013 respectively. The distribution of subjects and deaths by study and CD4 count is shown in Table 1. The mean baseline CD4 count was 73 cells/uL higher (95% CI: 56, 89; $p < 0.001$) in 2013 (199 cells/uL) vs. 2006 (126 cells/uL). The difference in mean CD4 remained approximately the same (72 cells/uL) when controlling for sex and age. Within 6 months of enrollment, 18 participants died in the 2006 cohort and 20 participants died in the 2013 cohort. The incidence rate of death was 11.7 in 2013 and 10.7 in 2006 per 100 person-years (IRR=1.1, 95% CI: 0.55, 2.2). The hazard ratio (HR) of death comparing 2013 to 2006 was 1.1 (95% CI: 0.57, 2.0; $p = 0.832$). When adjusting for baseline CD4 count, age and sex, the HR was 1.27 (95% CI: 0.57, 2.8, $p = 0.551$). Higher CD4 count was significantly associated with a lower risk of death in all models ($p < 0.01$).

Conclusions: With implementation of guidelines to initiate ART at a CD4 ≤ 350 cells/uL, the mean CD4 count increased among those accessing care to initiate ART, though 6-month mortality remained approximately the same. Despite new guidelines, many participants initiated ART with dangerously low CD4 counts. Earlier HIV diagnosis and rapid linkage to care is necessary to achieve survival gains from new ART guidelines.