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Treatment discontinuation in HIV-1-infected individuals starting their first-line HAART after 2008: data from the ICONA Foundation Study Cohort

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Introduction: The aim of this study was to analyze the likelihood and the predictors of discontinuation of first-line regimen in the late HAART era.

Methodology: An observational multi-center analysis of HIV-positive patients enrolled in ICONA. Patients eligible were those starting a first-line HAART after 1 January 2008. Discontinuation was defined as stop and/or switch of at least one drug of the regimen. All causes of discontinuation, as reported by the treating physician, were evaluated and cumulative risk of stopping was investigated according to age, gender, co-morbidity, years since starting HAART, immuno-virological status, third drug and backbone of the first regimen. Kaplan Meier (KM) analysis and Cox proportional hazards model were used for the outcome discontinuation of ≥ 1 drug regardless of the reason. For the KM estimates a competing risk approach was used to estimate the contribution of each of the reasons over time to the cumulative risk of stopping over time.

Results: Data of 1759 patients who started first HAART and had at least one month of clinical follow-up were analyzed. The overall discontinuation risk was 33% over a median follow-up of 12 months. The likelihood of discontinuation by KM was 27% by one year (95% CI 25–29) and 41% by two years (95% CI 38–44). Main reason for stopping at least one drug in regimen was simplification (10%), followed by intolerance (7%), toxicity (5%), failure (2%) and other causes (8%). Estimates of the cumulative risk of discontinuation of ≥ 1 drug over time and according to reason are shown in Figure 1. In a multivariable Cox model independent predictors of discontinuation regardless of the reason were: longer time from HIV diagnosis to date of starting

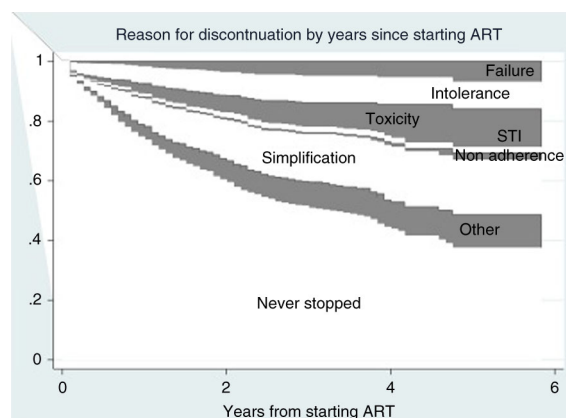


Figure 1. Reason of discontinuation.

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HAART (hazard ratio [HR] 0.96; 95% CI 0.93–1.00; $p = 0.039$), regimens containing ZDV/3TC (HR 2.86; 95% CI 1.42–5.76; $p = 0.003$ vs TDF/FTC) and an NNRTI-based regimen (HR 2.47; 95% CI 0.91–6.72; $p = 0.07$ vs regimens not NNRTI-based).

Conclusions: In a previously reported analysis of the ICONA data [1], the overall risk of discontinuation of first-line HAART was 36% with 21% due to intolerance/toxicity. In this updated analysis, the main reason for stopping is simplification (accounting for 32% of stops), reflecting the recent changes in recommendations aimed to minimize drug toxicity, enhancing adherence and quality of life.

Reference

1. d'Arminio Monforte A, Lepri AC, Rezza G, Pezzotti P, Antinori A, Phillips AN, et al. Insights into the reasons for discontinuation of the first highly active antiretroviral therapy (HAART) regimen in a cohort of antiretroviral naive patients. *AIDS*. 2000;14:499–507.