

## Abstract 109

### *Outstanding outcome: in whom and how*

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**Objective:** to evaluate the frequency of therapy failure and to identify baseline and time dependent factors associated with it in patients of ICONA Foundation Study.

**Methods:** a strict definition of therapy failure was applied to a large cohort of HIV positive patients ARTnaive at the baseline; it included virologic failure (first VL >200 copies/ml after 6 months of HAART leading to treatment change, or first value >1000 copies/ml or failure to reach undetectability), immunologic failure (first CD4 reduction >15% of baseline) and clinical failure (any ADE, cancer, serious CV or grade 4 laboratory event or death). Four Cox regression models were used.

**Results:** 3579 events (virologic failure 49.4%, toxicity 30.5%, AIDS 6.3%, immunologic failure 4.7%, non- AIDS defining events 2.1%, death 2.0%, mix of previous cause 5.0%) were observed in 6702 patients for 14742 PYFU. Patients were representative of the Italian HIV+ population. Overall the KM estimate of being free of events was 40.3% (95%CI 39-42) and 25.9% (95%CI 14-28) by 5 or 10 years, respectively (figure). Limiting the analysis to the years after 2000 the KM estimate raised to 50.5% (95%CI 48-53) by 5 years. Baseline characteristics independently predictive of an event were male gender (Adjusted Hazard Ratio, AHR 1.11 vs. female; P=0.028); CDC C class (AHR 1.31 vs. CDC A/B; P<0.001); infection's years (AHR 1.01; P=0.008 per year longer); HCV+ (AHR 1.26 vs. HCV-; P<0.001) and HBV+ (AHR 1.35 vs. HBV-; P<0.001) or being on a first-line other than a NNRTI-based regimen (AHR from 1.31 to 1.67; P=0.015), while white ethnicity (AHR 0.68 vs. other; P<0.001) and having started HAART after 2000 (AHR from 0.69 to 0.80; P=0.002) were protective. Baseline CD4 counts and HIV-RNA did not correlate with the outcome. For time-dependent variables, assessed in three different models, undergoing repeated switches (AHR 1.06; P=0.01 per additional switch) was a negative predictor, while longer time with HIV-RNA <200 copies/ml or CD4 > 500 cells/ml were positively correlated (AHR 0.64; P<0.001 per year longer; and AHR 0.93; P<0.001 per year longer).

**Conclusions:** A completely positive or optimal outcome pertains to 26% of patients at 10 years. It seems possible to identify patients who are more likely to have favourable long-term outcome on treatment. These include: female gender (possible proxy of more controlled lifestyle), white ethnicity (possible indicator of more regular accessibility to health system) absence of co-infections. Noteworthy, patients starting HAART recently had an higher chance for optimal outcome (up to 50% at five years); this observation easily reflects the improvements of ART therapy. Similarly it is interesting that the first therapeutic choice influences the outcome although this must be cautiously evaluated as channeling biases may be present.

Nonetheless, a steadily control of HIV replication and a lower need of therapeutic switches do positively influence the outcome.