Code: PE8/43

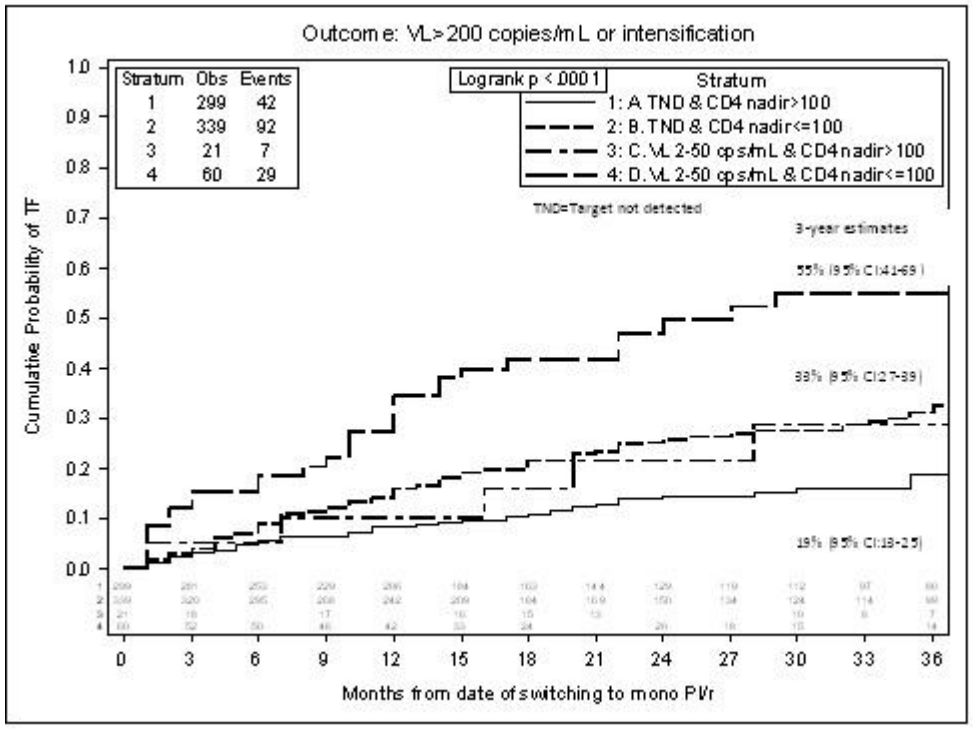
Abstract: 556

Risk and Determinants of Failure of a Mono-PI/r Simplification Strategy with LPV/r or DRV/r in Clinical Practice

A. Cozzi-Lepri[1], N. Gianotti[2], A. Antinori[3], A. Castagna[2], A. De Luca[4], B.M. Celesia[5], M. Galli[6], C. Mussini[7], C. Pinnetti[3], V. Spagnuolo[2], A. d'Arminio Monforte[8], M. Andreoni[9], on behalf of Icona Foundation Study and Mono-PI/r Database Study Cohorts

[1]University College London, London, United Kingdom, [2]San Raffaele Hospital, Milano, Italy, [3]INMI Spallanzani, Roma, Italy, [4]University of Siena, Siena, Italy,[5]University of Catania, Catania, Italy, [6]Sacco Hospital, Milano, Italy, [7]University of Modena and Reggio Emilia, Modena, Italy, [8]San Paolo University Hospital, Milano, Italy, [9]University of Tor Vergata, Roma, Italy

Objectives: To identify key predictors of failure of mono-PI/r simplification therapy with LPV/r or DRV/r.
Methods: We included patients either of the Icona Foundation Study or ART-experienced patients attending Icona sites (monoDB) who switched to a mono-PI/r simplification with LPV/r or DRV/r with a viral load (VL)≤50 copies/mL. The outcome was time to treatment failure (TF) (virological failure (VF)>200 or discontinuation of the PI/r or intensification with other drugs). Based on previous evidence, 8 main predictors were considered: CD4 count at time of switch, CD4 count nadir, duration of VL suppression, history of VF to PIs, HCV co-infection, taking PI/r in cART prior to switch, haemoglobin at switch, residual VL at switch. Kaplan-Meier (KM) estimates are given. Multivariable Cox regression was constructed using stepwise (backward and forward) as well as 'best subset' selection.
Results: We identified 719 individuals (202 from Icona and 517 from monoDB; 294 switched to LPV/r and 425 to DRV/r). Median (IQR) nadir CD4 count and duration of suppression were 357 (208;630) cells/mm3 and 44 (20;75) months, respectively. By 3 years from the switch, pure risk of VF was 8% (95% CI: 6-11) and risk of TF was 29% (95%CI:25-33). Stepwise approaches removed all considered predictors but CD4 count nadir and residual viremia. This bivariate model was the best choice also when using the 'best subset' selection with adjusted relative hazards (RH) of 2.05 (95% CI:1.33- 3.16) comparing CD4 nadir≤100 and >100 cell/mm3 and RH=1.76 (1.23-2.52) comparing 2-50 copies vs. target not detected (TND). The figure shows KM estimates of TF by strata.
Conclusion: In our large clinical setting, mono PI/r simplification strategy showed a risk of TF consistent with that observed in clinical trials. Residual VL≤1 copies/mL of detection and CD4 count nadir >100 cells/mm3 should be considered the main factors to guide selection of patients.



[Figure. Kaplan-Meier estimates of TF according to]