

Poster Abstract – P263

Effectiveness of first-line antiretroviral therapy based on NNRTIs vs ritonavir-boosted PIs in HIV-1 infected patients with high plasma viral load

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Purpose of the study

Few clinical trials have compared non-nucleoside reverse transcriptase inhibitors (NNRTI) and ritonavir-boosted protease inhibitors (PI/r) as initial combined antiretroviral therapy (cART) for HIV-1-infected patients with high plasma viral load (pVL), and non-conclusive results have been reported. We compared the effectiveness between NNRTI and PI/r as first-line cART for HIV-1-infected patients with high pVL.

Methods

Observational retrospective study of 664 consecutive treatment-naïve HIV-1-infected patients with pVL (HIV-1 RNA) >100,000 copies/mL who initiated NNRTI or PI/r-based cART between 2000–2010 in three University hospitals. Only currently preferred or alternative regimens in clinical guidelines were included. Primary endpoint: percentage of therapeutic failures at week 48. Virologic failure was defined as: a) lack of virologic response (<1 log RNA HIV-1 decrease in first 3 months); b) RNA HIV-1 >50 c/mL at week 48; c) confirmed rebound >50 c/mL after a previous value <50 c/mL. Intent-to-treat (ITT noncompleter = failure) and on-treatment (OT) analyses were performed.

Results

62% of patients initiated NNRTI-regimens (83% efavirenz) and 38% PI/r-regimens (62% lopinavir/). Baseline characteristics: male 83%; median age 39 yrs; median CD4 count: 212/μL (NNRTI 232 vs PI/r 177, $p = 0.028$); pVL 5.83 log₁₀ c/mL (NNRTI 5.43 vs PI/r 5.55, $p = 0.007$); AIDS 24% (NNRTI 21% vs PI/r 29%, $p = 0.015$). NRTI backbones were tenofovir plus 3TC or FTC in 72%. The percentage of therapeutic failure was higher in the PI/r group (ITT NC = F 26% vs 18%, $p = 0.012$) with no differences in virologic failures (PI/r 5%, NNRTI 6%, $p = 0.688$). The rate of treatment changes due to toxicity and/or voluntary discontinuations was higher in the PI/r group (15% vs 8%, $p = 0.008$). A multivariate analysis adjusted for age, gender, CD4 count, VL and AIDS showed NNRTI vs PI/r as the only variable associated with treatment response (OR 0.61, 95% CI 0.41–0.88). Median pVL and rate of resistance at virologic failure were higher in patients receiving NNRTI (3.97 vs 2.49 log copies/mL, $p < 0.001$ and 62% vs 12%, $p = 0.004$, respectively).

Conclusions

Initial NNRTI-regimens showed higher effectiveness compared with PI/r-regimens in HIV-1-infected patients with high pVL, although virologic failure rates were low and comparable. Resistance emergence was more frequent and pVL higher in patients failing NNRTI. However, more patients initiating PI/r-based regimens changed or discontinued therapy.

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