



Nelfinavir versus Indinavir/Ritonavir in Treatment Naïve Patients : Comparison of Efficacy and Safety at One Year

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OBJECTIVE : To compare the efficacy, rate of treatment discontinuation and impact on lipid profile of nelfinavir (NFV)-based versus boosted-indinavir (IDV) -based triple combination in naïve patients (p.).

METHODS : All p. starting NFV (1250mg BID, g1) or IDV-ritonavir (RTV) (800-100mg BID, g2) with 2 NRTIs were selected. Data on viral load (VL), CD4 and safety were collected prospectively every three months (M). Intent-to-treat (ITT) (missing=failure for VL and CD4) and on-treatment (OT) analyses were performed at M12. The relationship between treatment group and time to switch was studied using the Cox model and adjusted on sex, age and viral load. Time to treatment switch was computed using Kaplan-Meier estimates.

RESULTS : From 01/99 to 11/00, 69 p. (g1) and 44 p. (g2) were retrieved. 57% were female, 68% Africans, 82% heterosexual, median (md) VL was 4.8 log and md CD4=209 cells/mm³. Both groups were comparable for all parameters. There were no statistical significant differences at M12 on proportion of p. with VL < 50 (ITT: 64% vs 70%, OT: 77% vs 87%) and on md CD4 (ITT: 404 vs 387, OT: 404 vs 223). Treatment was discontinued by 25/69 p. (36%) vs 21/44 p. (63%), p<.005. NFV-based therapy adjusted on sex, baseline VL and age was associated with a lower risk of switch (hazard ratio of switch=0.46, 95% confidence interval limits=0.26;0.84) (p<.02). Mean time to occurrence of switch was 290 (standard error (SE) 14) and 206 (SE 21) days in g1 and g2 respectively (Log-Rank test p<.002). Discontinuations due to side effects (mainly digestive) occurred in 8/25 p. (32%) vs 16/21 p. (76%). Rates of p. with at least one grade increase of cholesterol and triglycerides were : ITT, 16% vs 11%, 30% vs 41%; OT, 18% vs 19%, 39% vs 62%.

CONCLUSIONS : These two BID PI-based combinations were similar in terms of efficacy and impact on lipids at one year. However, the rate of treatment discontinuations was significantly higher in the indinavir group and mainly due to side effects.

Abstracts