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Switching to nevirapine-based HAART in virologically-suppressed patients: influence of a longer twice-daily induction period on once-a-day dosing

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Purpose of the study

We are conducting a multicenter, randomized, controlled, prospective, open trial to evaluate both the efficacy and toxicity of nevirapine (NVP) (given twice [BID] or once daily [QD]) in virologically-suppressed patients on a PI-based HAART. NVP BID dosing is maintained for 2 months after the switch in both groups.

Methods

Patients with >6 months of plasma HIV-RNA (pVL) undetectability (<50 copies/mL) while on therapy with a PI (boosted or unboosted) plus two NRTIs were considered for enrolment. Co-infection with HCV and/or HBV was allowed. All patients were to receive NVP 400 mg/day on a bid schedule for 2 months and then should be randomized to continue (group A) or to switch to a QD schedule (group B). The NRTI backbone could either be maintained or changed during the study.

Summary of results

The study enrolled 126 patients (63 in each group). Database was frozen on June 30, 2008, and an interim analysis was done on 119 patients whose data are available on the internet-based CRFs. Males are 90%, mean age was 45 ± 8.9 years, 93.1% are Caucasians, 37.8% had AIDS, 24.7% are HCV+. HIV-RNA pVL result undetectable since mean of 28 months before switch. At baseline CD4s were 531 ± 262/mm^3, total cholesterol 202 ± 49.2 mg/dL, triglycerides 216 ± 140.3 mg/dL, ALT 33 ± 22.6 U/L, and gamma-GT 53 ± 69.6 U/L (all means ± SD). No statistically significant differences were present between groups at switch. After 6 months, mean values in group A vs. B were respectively: CD4s 578 ± 290 and 573 ± 261/mm^3; cholesterol 204 ± 42.6 and 195 ± 39.9 mg/dL; triglycerides 135 ± 69.3 and 142 ± 81.7 mg/dL; ALT 51 ± 47.4 and 50 ± 44.3 U/L; gamma-GT 124 ± 120.9 and 123 ± 176.9 U/L (p values: all NS). We have so far recorded five virological failures (four in group A – two at 3rd and two at 4th month, one in B at 4th month). Five patients (three in group A; two in group B) had grade-4 adverse events (AEs) in the first 2 months after switch (when both groups were treated with NVP bid): three episodes of hepatotoxicity (two in HCV+), one rash (in a black woman), and one for headache and dizziness. Three additional hepatotoxic grade-4 AEs occurred afterwards: two in group A (6th month) and one in B (3rd month), all in patients without HCV/HBV co-infections.

Conclusion

In a switch strategy, NVP given BID or QD seems to be equally effective and tolerated at this interim analysis. The influence of a BID induction period on QD dosing would be fully assessed when all data will be available.