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Raltegravir therapy in HIV multi-experience patients: safety and efficacy

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Purpose of the study

To evaluate efficacy, tolerability and safety of raltegravir (expanded access program) in HIV multi-experience patients.

Methods

Observational study to analyse immune and virological response, and incidence of adverse events during raltegravir therapy. Transaminase elevation(TE) was scored according to increase in ALT value 2.6–5× upper normal limit (toxicity grade 2), 5.1–10× upper normal limit (toxicity grade 3) and >10× upper normal limit (toxicity grade 4). To avoid bias related to patients with high baseline serum ALT and AST levels, TE was defined by increase in ALT value 2.6–3.5× (toxicity grade 2), 3.6–5× (toxicity grade 3), and >5× (toxicity grade 4) the baseline value. Metabolic and renal profile were assessed at baseline, after 1 month and every 3 months. 103 HIV+ patients have been enrolled; 37 patients were HCV or HBV co-infected. CDC group was 50C, 34B and 19A. Previous therapeutic mean lines was 9.1; mean mutations were 5.5 for NRTI and 8.6 for PI.

Summary of results

Mean follow-up is 177 ± 80 days (range 55–450). Five patients stopped all HIV therapy for personal decisions without side-effect. Most frequent associated protease inhibitor was darunavir (77 patients) and 10 patients had TMC125 and seven had T20 associated with raltegravir. Mean CD4 and HIV-RNA values at baseline were 279 cells/mm3 and 3.89 log cp/ml, respectively; during the follow-up there was an increase of CD4 count (344 cells/mm3) and a decrease in viral load (1.69 log) which was statistically significant ($p < 0.0001$). One patient had no viral suppression and four patients had a viral failure (HIV-RNA<1,000 cp/ml) after 6 months of therapy. Only two HCV-positive patients had an increase in transaminase value grade 2. One patient developed NH lymphoma, One patient had an acute myocardial infarction and one patient in dialysis underwent to renal transplantation; none of the patients stopped raltegravir. No statistically significant modification has been seen in ALT, AST, GGT, creatinine, glucose, triglycerides values. Only total cholesterol showed a statistically significant increase ($p = 0.0115$ and $p = 0.0442$) at 3 (196 mg/dl) and 6 (189 mg/dl) months, probably due to boosted protease inhibitor association; 48 patients had at baseline cholesterol values in the upper normal limit and the lipid profile did not worsen during follow-up.

Conclusion

Raltegravir was well tolerated and efficient in all patients and showed a good metabolic, renal and liver profile in our cohort where the rate of co-infected patients was high.