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Efficacy and safety of switching enfuvirtide to raltegravir in patients with viral suppression

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Purpose of the study

Among the currently available antiretroviral drugs, the novel integrase inhibitor raltegravir (RAL) is an oral agent without cross-resistance to any other antiretroviral family and it provides an option with easier administration and better tolerability than enfuvirtide (ENF). There is no experience in routine clinical practice with RAL as a simplification strategy. We evaluate the efficacy and safety of switching ENF to RAL as a simplification strategy for a follow-up of 24 and 48 weeks in patients with an HIV-1 viral load (VL) < 50 copies/mL.

Methods

In this retrospective cohort, patients from routine clinical practice on a suppressive ENF-containing regimen were selected. The patients were switched from ENF to RAL while the rest of the antiretroviral regimen remained unchanged. According to standard clinical practice, we assessed the VL, CD4+ T-cell count, hepatic enzymes and fasted lipid profile. Results after a 24-week period of follow-up are shown in this analysis. Sixteen patients were included in this analysis. At baseline, the median number of prior antiretrovirals was 12 (9–16). The means of time on ENF treatment and time with viral suppression were 126 (SD: 62) and 98 (SD: 57) weeks, respectively. The concurrent treatments included DRV/r in 10 (62.5%) patients, TPV/r in five (31.2%) and ETV in two (12.5%) more subjects. The 100% of patients achieved 24 weeks with sustained viral suppression. Median CD4+ T-cell count increased from 374 (272–466) cells/mL at baseline to 408 (308–541) cells/mL at week 24 of follow-up (p = 0.087). There were no significant changes in total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides (p = 0.103, p = 0.934, p = 0.978 and p = 0.696, retrospectively). Similarly, there were no significant changes in AST, ALT and ALP (p = 0.156, p = 0.475 and p = 0.487, respectively). Only the gamma-GT improved significantly, showing a reduction from 58.5 (32.2–78.7) U/L at baseline to 37 (22.5–54) U/L at week 24 of follow-up (p = 0.023). Injection site reactions were solved in all patients after switching and there were no significant adverse events related with RAL administration.

Conclusion

Switching ENF to RAL seems to be safe and effective in the short-term in patients with viral suppression despite a prior high antiretroviral experience. Its long-term impact on patient's adherence, quality of life, safety and efficacy should be evaluated in clinical trials.