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Switch from enfuvirtide (ENF) to raltegravir (RAL): a simplification option for heavily pretreated HIV patients (pts)

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Purpose of the study

ENF was the first HIV entry-inhibitor approved by the FDA in 2003, which offered hope to many pretreated pts on a failing antiretroviral (ARV) regimen; but ENF is difficult to take since it requires reconstitution, parenteral administration and it causes local reactions at injection sites. Raltegravir (RAL) is the first commercially available HIV-integrase inhibitor; BENCHMARK 1–2 studies demonstrated its efficacy in treatment-experienced pts harbouring multiresistant HIV strains especially when associated with ENF in ENF-naïve pts. The aim of this analysis was to longitudinally evaluate the viro-immunological and safety outcome of experienced patients switching from ENF to RAL in order to simplify the treatment schedule which may be often very complicated in 'salvage' therapy.

Methods

Pts were enrolled during the expanded access programme of RAL in the outpatient HIV clinic of Brescia. Viral load (VL, bDNA), CD4 cell count, AST, ALT, total cholesterol (TC), tryglicerides (TG) and glycemia were recorded at baseline (BL) and every 3 months (T3, T6); results are expressed as median (range); parametric and non-parametric tests have been used for comparison of continuous variables between groups when appropriate ($p < 0.05$ considered significant).

Summary of results

Fifteen pts (males 86.7%; average age 45 yrs(40–72), median RAL exposure 6 months (3–8) were considered for this analysis. All were taking a boosted protease inhibitor (darunavir 15/16, fosamprenavir 1/16); the backbone was formed by tenofovir/emtricitabine in 11/16. Median ARV therapy and ENF exposure before switch to RAL was respectively of 166 (125–184) and 14 (range 3–26) months. Viro-immunological and biochemical data are summarized in Table 1. No statistically significant difference was found between BL and T3 or T6 values for any of the parameters analyzed while at BL, VL was detectable in 3/15 (20%), at T3 only in 1/15 (6%), and in none of the evaluable patients after 6 months was a detectable VL found. The CD4 cell count showed a trend toward an increase with a stability of CD4 percentage.

Conclusion

The switch from ENF to RAL was efficacious and well tolerated in a small cohort of heavily pretreated HIV pts; this ARV change may represent a sort of 'simplification' option for multiresistant pts taking ENF with at least another active drug in the regimen.

Table 1:

Variable	BL (n = 15)	T3 (n = 15)	T6 (n = 11)
VL (copies/mL)	50 (50–251.967)	50 (50–296)	50 (50–50)
CD4 cell count (cells/mL)	170 (53–496)	206 (91–494)	213 (101–555)
CD4+ %	16.9% (7.8–27.3)	19.8 (7.2–27.1)	16.1 (6.5–21.1)
AST (UI/L)	35 (13–75)	39 (18–108)	34 (15–146)
ALT (UI/L)	53 (18–162)	52 (15–166)	59 (15–224)
TC (mg/dL)	164 (123–269)	180 (113–232)	166 (85–257)
TG (mg/dL)	176 (62–363)	171 (46–339)	192 (33–402)
Glycemia (mg/dL)	92 (74–212)	90 (77–198)	91 (76–208)