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Poster presentation

Raltegravir: a potent and safe integrase inhibitor with a favourable impact on cardiovascular and liver profile

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Purpose of the study

Raltegravir (RAL) is the first marketed HIV integrase inhibitor. It has shown considerable potency and safety in clinical trials conducted in antiretroviral (ARV)-experienced HIV+ patients. This study aims to assess the performance of RAL in a routine clinical practice, as part of therapeutic strategies besides salvage therapy.

Methods

Retrospective longitudinal assessment of all HIV+ patients who received RAL at our institution until June 2008. Overall, the drug was prescribed as part of a salvage regimen or in patients with undetectable plasma HIV-RNA under another regimen as part of a switch strategy due to intolerance or toxicity to the previous combination. Data were recorded at baseline and during 48 weeks of follow-up.

Summary of results

A total of 106 patients were analysed. Mean age 46 (± 7) years, male 80%, IDUs 45% and MSM 35%; HBsAg+ 9%, HCV-RNA+ 32%. Mean time on ARVs: 9.7 (± 3.7) years. In 62 patients, RAL was part of a salvage regimen, being other active drugs (one in 56%, ≥2 in 23%): darunavir 40%, tenofovir 21%, atazanavir 10%, and etravirine 6%. Baseline plasma HIV-RNA and CD4 counts were [median (IQR)]: 3.8 (2.9–4.4) log10 copies/ml and 252 (156–418) cells/μL, respectively. After 1 month, median plasma HIV-RNA declined 1.94 log10 and 75% of patients reached <50 copies/ml. In the 44 patients in whom RAL was used due to convenience (n = 6), intolerance (n = 16) or toxicity to other ARVs (n = 22), the most commonly switched drugs were atazanavir/r (31%), T-20 (16%) and lopinavir/r (10%). None of the 44 patients failed virologically on RAL during follow-up. CD4 counts increased a median of 45 cells/μL.

In all 106 patients on RAL, no serious adverse events occurred and treatment adherence was >95%; laboratory parameters including liver enzymes and lipids did not significantly change during follow-up.

Conclusion

Outside clinical trials, RAL shows a remarkable virological and immunological efficacy as part of salvage regimens, as well as in switch strategies in patients with undetectable viremia experiencing intolerance or toxicity to other antiretrovirals. Since the drug is safe and well tolerated, it may be worth to consider its use in earlier HIV stages, particularly in patients with cardiovascular risk and/or viral hepatitis. (Table 1.)

References

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2. Harris M, Larsen G, Montaner JS: **Outcomes of multidrug-resistant patients switched from enfuvirtide to raltegravir within a virologically suppressive regimen.** *AIDS* 2008, **22(10):**1224-6.

Table 1:

	Baseline	3 months	6 months	9 months	12 months
SALVAGE THERAPY	n = 62	n = 39	n = 27	n = 21	n = 9
ΔpHIV-RNA log10 cop/mL	0	-1.8 (-2.6 – -1.2)	-2.1 (-2.7 – -1.3)	-2 (-2.6 – -1.2)	-2.4 (-2.7 – -1.3)
%pts pHIV-RNA<50 cop/mL	0	84	85	86	67
ΔCD4+ cells/μL	0	62 (0–118)	38 (4–61)	82 (20–148)	88 (28–184)
NO SALVAGE THERAPY	n = 44	n = 20	n = 10	n = 4	-
%pts pHIV-RNA<50 cop/mL	100	100	100	100	-
ΔCD4+ cells/μL	0	27 (-8 – +70)	45 (-3 – +98)	13 (-38 – +202)	-
ALL PATIENTS	n = 106	n = 59	n = 37	n = 25	n = 9
Hb g/dL	14.9 (13.7–15.9)	14.9 (13.8 – 16.5)	15.3 (14.2–16.3)	15.4 (14.8–16.4)	14.8 (13.2–16.3)
Glucose mg/dL	98 (92–110)	99 (91–108)	99 (91–104)	99 (92–106)	98 (91–107)
Creatinine mg/dL	0.9 (0.8–1)	0.9 (0.8–1)	0.9 (0.8–1)	0.9 (0.9–1)	0.9 (0.8–1)
AST IU/L	32 (24–50)	29 (25–41)	28 (22–51)	27 (23–34)	31 (22–43)
ALT IU/L	31 (21–62)	32 (23–46)	27 (20–61)	27 (18–39)	28 (21–68)
Total bilirubin mg/dL	0.8 (0.6–1.3)	0.7 (0.6–1)	0.8 (0.6–1.2)	0.8 (0.6–0.9)	0.8 (0.6–0.9)
Total cholesterol mg/dL	185 (147–208)	190 (160–224)	190 (171–217)	201 (176–224)	193 (154–222)
HDL cholesterol mg/dL	33 (26–43)	39 (31–47)*	38 (31–48)	36 (30–44)	33 (28–42)
LDL cholesterol mg/dL	119 (86–132)	124 (84–146)	124 (106–147)	134 (112–147)	137 (104–157)
Triglycerides mg/dL	120 (71–198)	122 (91–163)	136 (69–175)	137 (102–208)	120 (63–143)

All values are expressed as median (IQR), unless otherwise indicated. *p < 0.05 compared to baseline.