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Poster presentation

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Efficacy, safety and tolerability of enfuvirtide in a population of Portuguese HIV-1 chronically infected patients

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Purpose of the study

To assess efficacy, safety and tolerability of enfuvirtide (ENF), as part of an antiretroviral (ARV) regimen, in a heavily pre-treated, non-selected Portuguese population with chronic HIV-1 infection, without previous exposure to fusion inhibitors.

Methods

Multicenter, retrospective, 48-week (wk) observational study. Inclusion criteria allowed adults with HIV-1 infection, with virologic failure and resistance to at least one drug of each ARV class (N(t)RTI, NNRTI, PI) who completed ≥ 48 wks of ENF, during the first half of study period.

Summary of results

93 patients were included and started ENF as a component of an optimized antiretroviral regimen. Baseline characteristics (median values): 80% male, age 45 years (25–70), 72% acquired HIV infection through sexual contact and 22% by intravenous drug use. Time since diagnosis 9 yrs (1–22), 69% had AIDS criteria, previous exposure to 10 ARVs (3–19) and 9 (1–16) yrs of treatment. Baseline median TCD4+ was 167/mcl (6–600), with sustained increase during the 48-wk study period and final gain of 150/mcl (2–742)(ITT).

The median HIV-1 RNA decrease, at wk 12, was 2.2 log10. At this time, 23.8% of patients presented with HIV-1 RNA <50 cp/ml, and by the end of study 53.2% were suppressed. Comparing with the predictive factors of treatment response identified in TORO trials, we did not find a statistically significant difference in the immunological response between the group of patients with previous exposure to <10 or ≥10 ARVs. Patients with baseline TCD4+<100/mcl showed better immunological responses, compared to those with higher values. Nevertheless, at wk 48, the difference was not statistically significant (p = 0.065).

Those patients with baseline viral load<100,000 cp/ml revealed a trend to better immunological response, but at wk 48 the difference did not reach statistical significance (p = 0.128).

Median Genotypic Susceptibility Score of the ARV regimen containing ENF was 1.5 (0–3).

20/93 (23%) of patients had to change ARV regimen and 17/93 (18%) interrupted treatment with ENF mostly due to: injection site reactions (n = 5), poor adherence (n = 7) and virologic failure (n = 6).

Conclusion

These data from a real-life setting confirm ENF efficacy, safety and good tolerability in a non-selected patient population. Compared to TORO trials, this population achieved a better virological response, probably explained by the favorable baseline characteristics previously defined as predictive factors of successful treatment.