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Efficacy and safety of an antiretroviral regimen containing etravirine plus raltegravir in HIV-1 treatment-experienced patients failing darunavir

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Purpose of the study

To evaluate the efficacy of raltegravir (RAL) and etravirine (ETV) in addition to a background optimised treatment in patients (pts) with persistent viremia while on darunavir (DRV) and multidrug resistant virus.

Methods

Prospective, pilot, open-label, single arm study evaluating pts with at least 3-drug class exposure, plasma HIV-RNA (VL) >1000 c/ml while on a DRV-containing regimen. Pts were given RAL and ETV in addition to optimized background therapy (OBT). Primary end-point was the proportion of pts with a VL<40 c/ml at week 24.

Summary of results

Overall, 20 pts were enrolled. Baseline characteristics were as follows: median duration of prior ARV therapy 13 years [range: 6–20], median VL of 4.6 log10 [3.36–5.56], and median CD4 count of 254 cells/mm3 [63–833]. Eleven pts (55%) had prior enfuvirtide and four prior foscarnet. Excluding RAL and ETV, GSS was 0 for two pts, one for 11 (58%) pts, two for five (25%) pts and 3 for one pt. Fourteen pts (74%) had a virus with 1 NNRTI resistance mutation (median: 1 [0–3]), 14 (73%) were resistant to DRV, four (21%) had intermediate DRV sensitivity. The median number of antiretroviral drugs in the OBR was five [3–7], five (25%) received atazanavir and nine (45%) enfuvirtide.

At week 24, the proportion of patients with VL< 40 c/ml was 65% and the proportion <400 copies/ml 100%. The median decrease in viral load was -2.56 log10 [-3.78 – -1.01] at week 4, -2.87 log10 [-3.78 – -1.01] at week 12 and -2.90 log10 [-3.78 – -1.76] at week 24. The median increase in CD4 was + 80 [-29 – +485] cells/mm3 at week 24. At week 4, the median RAL Cmin in nine pts was 134 ng/ml [44–379], ETV: 374 ng/ml [86–785] and DRV: 3487 ng/ml [1442–4603]. Resistance testing was successful in 3/7 patients between 40 and 400 c/ml: none had RAL-associated mutations.

Conclusion

An unexpectedly high rate of virological success was observed in this pilot study of patients with very limited treatment options except RAL and ETV while failing darunavir.