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Single agent HAART with Lopinavir/r (LPV/r) in ART-naive and pre-treated HIV-1-infected patients

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Background

Side effects from and resistance against NRTI/NNRTI-containing regimens and the need to simplify successful HAART to improve compliance or to decrease toxicity are reasons to search for new therapeutic options. One approach is a single-agent-HAART with a well tolerated, highly potent protease inhibitor with a high genetic barrier to resistance. [1-4]

We evaluated virological outcome of LPV/r-monotherapy in different situations of daily practice.

Methods

- Two-site, prospective observational study.
- Entry criteria
  - No evidence for LPV/r-resistance according to the ANRS AC11 rules (ANRS V2004.09 and ANRS V2005.07) based on genotypic resistance test prior to LPV/r-monotherapy and one of the following indications for LPV/r-monotherapy:
    - therapy-naive patients with anxiousness about facial lipoatrophy
    - failing NRTI/NNRTI-regimens
    - NRTI/NNRTI-side effects
    - simplification of a successful HAART

Results

Study Population

- 63 patients were accrued between 2002 and 2005.
- 13% were therapy-naive, 41% had unfavorable side effects under NRTI, 19% with the need to simplify the regimen and 27% with failing regimens.
- Mean age 45 years (range 29-76 years)
- Gender male 51 81%
  female 12 19 %
- Infection mode
  MSM 33 52%
  IVDU 19 30%
  Pattern II 7 11%
  other 4 7%
- CDC-staging A1-3 38%
  B1-3 44%
  C1-3 18%
- The 55 pre-treated patients had a mean duration of 6.1 years of prior HAART (range 1-12 years).
  The mean number of antiretrovirals taken prior to LPV/r-monotherapy was 5.6.
  - # of patients with NRTI/NtRTI 54 98%
  - # of patients with NNRTI 32 58%
  - # of patients with PI 33 60%

Follow-up

At last follow-up, the mean duration of LPV/r monotherapy was 14 months (range 1-42).

Median changes in triglycerides and total cholesterol were +41 and +27 mg/dl, respectively.

Virological and immunological results

At the last observation time point (LOCF, last observation carried forward), 73% (66%) of patients had a viral load <400 (<50) cop/ml. The mean increase of CD4-count was 106/µl.

	n / mean	range / %
HIV-PCR baseline [cop./ml]	68 000	0 – >750 000
HIV-PCR LOCF [cop./ml]	32 000	0 – >750 000
# of pts with HIV-PCR < 400 baseline	20	32%
# of pts with HIV-PCR < 50 baseline	17	27%
# of pts with HIV-PCR < 400 LOCF	46	73%
# of pts with HIV-PCR < 50 LOCF	42	66%
CD4 baseline	435	62 – 1692
CD4 LOCF	541	120 – 2475

- One PI-naïve patient developed primary PI-resistance while on LPV/r-monotherapy (described elsewhere as a case report [5]). Genotyping at month 12.5 revealed the PI-mutations L19I, S37N, M46I, I54V, V77I and I84V.
- Two patients with failing LPV/r-monotherapy did not meet entry criteria due to pre-existing PI-resistance.

Conclusions

Single agent HAART with LPV/r allows to maintain long-term virological control and an increase of CD4 count >100/µl in naive and pre-treated patients. Efficacy was comparable to standard triple therapy. Therapy was convenient; we did not see any severe side effects. Contrary to earlier studies, one PI-naive patient developed resistance to LPV/r.

References

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