

2001 and January 2004. All patients were followed until 180 days after initiation of ART. Incidence of skin rashes and clinical hepatitis after 1, 2, 3 and 6 months of ART were studied. Cox's proportional hazard model was used to analyse the possible risk factors.

Results: There were 785 patients with a mean age of 35.2 ± 7.4 years and 44% female. Median (IQR) CD4 cell count was 26 (8–76) cells/ μ L and median (IQR) baseline plasma HIV RNA was 268,000 (101,250–548,000) copies/mL. Incidence of NVP-associated skin rash grade II-IV at 1, 2, 3 and 6 months after ART were 5.7%, 7.4%, 7.7% and 7.7%, respectively. Incidence of clinical hepatitis at 1, 2, 3 and 6 months after ART were 0.5%, 0.8%, 0.9% and 1.2%, respectively. Cox's proportional hazard was used after adjusting for gender, baseline CD4 cells, log plasma HIV RNA and serum alkaline phosphatase; the result showed that every increment of baseline CD4 50 cells/ μ L was associated with higher incidence of NVP-associated skin rashes that lead to NVP discontinuation (HR = 1.431, 95% CI: 1.006–2.036, P = 0.046). The number of CD4 cell counts was not associated with NVP-associated clinical hepatitis.

Conclusions: HIV-infected patients with baseline CD4 <250 cells/ μ L had incidences of NVP-associated skin rashes grade II-IV and hepatitis that lead to NVP discontinuation approximately 8% and 1.2%, respectively. Almost all of events occurred within the first 3 months after ART. Even in HIV-infected patients with baseline CD4 <250 cells/ μ L, the higher number of baseline CD4 cells is associated with a higher risk for skin rashes

P1910 Potential role of TDM in dosing protease inhibitors in HIV-HCV co-infected patients with or without cirrhosis

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Objectives: to evaluate the influence of liver cirrhosis on pharmacokinetics (PK) of the main protease inhibitors (PIs) in HIV/HCV co-infected patients (pts) treated with atazanavir/ritonavir (ATV/r), fosamprenavir/r (FAPV/r) or lopinavir/r (LPV/r).

Methods: 39 HIV/HCV co-infected pts receiving ATV/r (14), LPV/r (13) and FAPV \pm r (12) were included.

According to liver stiffness (LS) value obtained by fibroscan[®] at the moment of PK determination or histological diagnosis patients were classified in 2 groups:

- NC, no cirrhosis (24) if LS < 12 kPa or Knodell fibrosis score (Kfs) 1–3;
- C, cirrhosis (15) if LS \geq 12 kPa or Kfs 4.

PIs plasma levels (PL) were determined by High Performance Liquid Chromatography. Samples for determination of C_{trough} (C_t) PL were collected before the morning or the daily dose at the steady state. Results are expressed as median (interquartiles); parametric and non parametric tests have been used for comparison of continuous variables between groups when appropriate ($p < 0.05$ was considered as significant).

Results: 35 pts had HIV-RNA < 50 and 4 < 2500 c/mL; 29/39 pts were on TDF+3tc/FTC. According to CHILD-PUGH score 10/15 C pts were classified as A5, 2 as A6 and 3 as B7.

LS in pts taking ATV/r, LPV/r and FAPV/r was respectively 6 (5–8), 6 (4–9) and 6.3 (5.9–6.9) kPa in NC and 17 (12–22), 34 (21–50) and 53.2 (48–75) kPa in C pts.

LS of C pts on FAPV was significantly higher than LS of C pts on ATV ($p = 0.0004$); C pts on FAPV were taking 700 mg BID according to DHHS guidelines.

Median C_t levels were 540 (170–990) in NC and 340 (100–460) ng/mL in C pts ($p = 0.3$) for ATV; 3020 (1020–4910) in NC and 3250 (1490–10100) ng/mL in C pts ($p = 0.6$) for LPV; 1350 (1020–1740) in NC and 210 (180–420) ng/mL in C pts ($p = 0.01$) for FAPV. Moreover PIs C_t was above minimum target concentration for wild-type virus (as suggested by DHHS guidelines) in all pts taking ATV/r, LPV/r and FAPV/r; this concentration was reached only in 2/5 C pts taking unboosted FAPV, both with a LS < 50 kPa.

Conclusions: ATV and LPV C_t doesn't seem to be affected by liver cirrhosis, while C_t of FAPV was found significantly lower in C with

respect to NC pts. Of note C pts on FAPV had a median LS significantly higher than others C pts and this may cause a reduction and/or diversion of the liver blood flow related to initial portal hypertension: dosing FAPV in C pts with a very high LS (>50 kPa) may therefore require TDM.

P1911 Immune recovery in treatment-naïve patients under HAART according to baseline CD4 count: the Chilean AIDS Cohort (ChiAC) experience

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Background: Immune recovery is one of the achievable goals of modern antiretroviral therapy (HAART) and is measured through CD4 counts which increase after successful viral suppression. The magnitude of recovery also seems to depend on baseline (BL) CD4 count, the higher the later, the better the results. Present guidelines recommend treatment before severe immunosuppression is present but many patients begin HAART with CD4 levels much lower than the recommended due to advanced disease at diagnosis.

Objective: To evaluate the rate of immune recovery in treatment naïve pts (TxN) initiating HAART at various levels of clinical and immunologic disease cared for in the Chilean Public Health System and followed by the ChiAC.

Methods: ChiAC has 4,500 pts under follow up, 52% TxN who initiated HAART between 10/2001 and 01/2004. Results from 2,429 TxN with information updated to 08/2006, with an average follow up period of 3.5 years were available. Variables studied were BL CD4 and CDC clinical staging, (A, B and C) HAART regimens and results. CD4 response was compared according to BL CD4 (Group [G] 1: 0–100, G2: 101–200 and G3: 201–300/mm³) both in absolute number (median) and slope and CDC BL clinical stage; CD4 results were measured every 6 months; Patients on HAART with BL CD4 > 300/mm³ were excluded; for statistical analysis SPSS 14 was used.

Results: At the beginning of HAART the number of patients in G1 was 1106; in G2, 712 and in G3, 304. Median baseline CD4 counts for each group were: 36 (SD \pm 29.0), 151 (SD \pm 28.4) and 232 (SD \pm 27) cells/mm³, respectively for groups 1, 2, and 3. Median CD4 rise were 137, 125, 188, 242 and 260 cells/mm³, at 0.5, 1, 2, 3 and 4 years of treatment respectively for G1; 69, 95, 193 and 239 cells/mm³ for G2, and 72, 74, 148, 228, 280 cells/mm³ for G3, respectively for these periods. The higher the BL CD4 the higher the CD4 rise over time but the slopes of the CD4 rise curves were comparable between groups. There was no difference in CD4 rise according to BL clinical status.

Conclusions: CD4 rise after successful HAART in treatment naïve pts was obtained at different levels of BL CD4 count, without significant difference according to BL clinical staging or viral load. The magnitude of the rise but not its rate is dependent on the BL CD4.

P1912 Efficacy and safety of tenofovir, abacavir and efavirenz in treatment-naïve patients: 48-week results (The ABATE Trial)

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Background: There are few data on the activity of tenofovir (TDF) plus abacavir (ABC) as a nucleotide/nucleoside backbone regimen in combination with efavirenz (EFV). The aim of this study was to evaluate the efficacy and safety of this combination.

Methods: This is a prospective and multicentre cohort study performed in nine Spanish HIV Units. Patients came from a randomised, multicentre, open-label, induction-maintenance clinical trial (the ABATE trial) in naïve HIV-1-infected patients with >100 CD4 cells/mm³ designed in 2002 and started in May 2003. Induction therapy was performed with TDF (300 mg, QD) plus ABC (300 mg, BID) plus EFV (600 mg, QD). Randomisation to maintaining or stopping EFV was planned at 6 months in patients with undetectable plasma RNA HIV-1 viral load (PVL) (<100 copies/mL). However, the DSMB recommended