

12th Annual Conference of the British HIV Association



29 March–1 April 2006, Brighton, UK

PROSPECTIVE TRIAL TO EVALUATE THE ROLE OF THERAPEUTIC DRUG MONITORING (TDM) IN HIV-POSITIVE PATIENTS STARTING/CHANGING ANTIRETROVIRAL (ARV) REGIMEN

HIV Med 2006; 7(Suppl. 1):14 (abstract no. P12)

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BACKGROUND: TDM is useful in specific clinical situations but its application in routine clinical practice is controversial. The study aim was to investigate the role of TDM in determining the need for ARV dose adjustments to ensure virological response or limit toxicity.

METHODS: In this non-comparative, prospective trial, patients starting NNRTIs or PIs had TDM at weeks 0/4/24/48. Dose adjustments were planned according to suggested target concentrations (TC) at 12 or 24 h (C_t) and clinical information (virological failure or drug-related adverse events).

RESULTS: 109 patients consented; 48 naïve, 61 switching regimen. Median (range) baseline HIV-RNA and CD4 were 2.76 (1.69–5.69) \log_{10} copies/ml and 279 (14–905) cells/ μ l. TDM results at week 0/4/24/48 were available for 49/ 77/50/23 patients. 40 patients received atazanavir/ritonavir (ATV/r), 23 efavirenz (EFV), 17 saquinavir/r (SQV/r), 14 lopinavir/r (LPV/r), 7 fosamprenavir/r (FPV/r), 1 nevirapine (NVP). Two patients on ATV/r, 5 on EFV, none on SQV/r, one on LPV/r, and none on FPV/r had a $C_t < TC$, none showed virological failure, no dose adjustment was performed. Three on EFV had $C_t > 4000$, but no major adverse event was reported and the patients continued EFV therapy. C_t inter-individual variability (coefficient of variation, CV%) was 51% for ATV/r and EFV, 91% for SQV/r, 42% for LPV/r, and 47% for FPV/r. Of 199 tests, 23 results were not interpretable due to frequent errors occurring when requesting TDM.

CONCLUSION: Despite wide variability in C_i , clinicians were reluctant to dose- modify in the minority of patients with abnormal results. TDM is a complex (though feasible) investigation to implement, and is frequently not performed correctly. The benefit of TDM in unselected patients is unclear, because patients with low C_i still responded to therapy.

2006-03-29
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