Test for CCR5 tropism and treatment with maraviroc in Sicily: an observational retrospective multicentre study

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Purpose of the study
Maraviroc (MVC) is the first CCR5 inhibitor licensed for clinical use. A pre-treatment test is mandatory to identify R5 tropic patients. Aim of this study is to detect indications and results of tropism test and to evaluate efficacy and tolerability of MVC-based regimen.

Methods
An observational retrospective multicentre study was performed in Sicily in 15 Infectious Diseases Units. Clinical records of 213 screened for tropism HIV+ subjects were reviewed for age, sex, risk, clinical stage (CDC, CD4 cell count, HIV RNA viral load), therapeutic line, indication and result of test for tropism; within subjects treated with MVC, HIV RNA, CD4 cell count and metabolic parameters trend and adverse events were analysed.

Summary of results
Median age 44 (IQR 30–50) years, 67.1% males; 46.3% heterosexuals, 28.6% MSMs, 21.4% IVDUs; 23.7% CDC A, 32.1% CDC B, 44.2% CDC C; median CD4 was 217 (IQR 121–374) cells/μl and mean of HIV RNA was 4.72 (CI 95% 4.07–4.67) log10 copies/ml; median therapeutic line was 4 (IQR 2–7). 80.8% were submitted to Trofile™ test, 19.2% to genotypic test, 75.5% after a therapeutic failure. 56.8% of subjects screened were R5, 7.5% X4, 21.6% DM, 14% undefined. All X4 patients were tested after a therapeutic failure; patients screened for toxicity were more frequently R5 (75%) (p <0.01). 76 (35.7%) multi-experienced (at baseline 8% HIV RNA <50 copies/ml, median CD4 cell count 219 (IQR 124–345) cells/μl) subjects were treated with MVC plus an optimized background treatment: MVC was associated in 74% of cases with a protease inhibitors (56% darunavir/ritonavir), in 42% with raltegravir, in 56% with a NUC-sparing regimen. After 12 months of treatment 56.8% (ITT analysis) and 61.7% (AT) of patients had HIV RNA <50 copies/ml; median CD4 cell count was 387 (IQR 222–455) cells/μl. After 24 months 64.8% (ITT) 80% (AT) had HIV-RNA <50 copies/ml. Median CD4 cell count was 381 (IQR 218.515) cells/μl with a median increase of 168 (IQR 54–274) cells/μl. At 24 months median value of total and HDL cholesterol and triglycerides were within the normal range. 7 patients stopped the treatment: 2 died, 1 adverse event, 4 virological failure.

Conclusions
Although the test has been proposed to patients with long treatment history and failure, only 3/5 of R5 tropic patients were treated with MVC. An high number of multi-experienced subjects treated with a MVC-based regimen obtained HIV RNA <50 copies/ml and a satisfactory increase of CD4 cell count.