



ORAL PRESENTATION

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The MONET trial: correlation between Hepatitis C coinfection and HIV RNA responses during darunavir/ritonavir monotherapy, for patients with HIV RNA <50 copies/mL at baseline

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Background

Co-infection with Hepatitis C has been associated with higher rates of treatment failure in cohort studies.

Methods

256 patients with HIV RNA <50 on current HAART for over 24 weeks (NNRTI based (43%), or PI based (57%), switched to DRV/r 800/100 mg once daily, either as monotherapy (n = 127) or with 2NRTI (triple therapy arm, n = 129). This sub-analysis investigated the effect of Hepatitis C co-infection on HIV RNA levels during the trial.

Results

At baseline, more patients were HCV antibody positive by serology in the DRV/r arm (17%) than in the control arm (9%). In the primary efficacy analysis at Week 48, 86.2% of patients in the monotherapy arm and 87.8% in the triple therapy arm had HIV RNA <50 copies/mL. Only four of the confirmed elevations in HIV RNA were above 400 copies/mL (two in each arm). In multivariate analysis (Per Protocol), hepatitis C co-infection was a significant predictor of confirmed HIV RNA elevations ($p < 0.01$). For patients infected only with HIV (HCV antibody negative at baseline), the percent HIV RNA <50 was 88.1% in the monotherapy arm versus 87.3% in the triple therapy arm. For patients HCV antibody positive at baseline, the percent HIV RNA <50 was 61.9% for the monotherapy arm versus 58.3% for the triple

therapy arm. Three patients had acute HCV infection during the trial (all in the DRV/r arm): all three had HIV RNA elevations at the time of acute HCV infection.

Discussion

In this study for patients with HIV RNA <50 copies/mL at screening, switching to DRV/r monotherapy showed non-inferior efficacy versus 2NRTI + DRV/r. Hepatitis C co-infection was more prevalent in the DRV/r monotherapy arm, and was a significant, independent predictor of transient, low-level HIV RNA viraemia. Hepatitis C co-infection might be a marker of poor adherence, or might be directly correlated with HIV RNA viraemia.

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