P1913
Poster Session VI
Viral hepatitis and HIV/HCV co-infection

SILIBININ PRIOR TO TRIPLE THERAPY LEADS TO END OF TREATMENT SUCCESS IN MOST DIFFICULT TO TREAT HIV/HEPATITIS C CO-INFECTED PATIENTS

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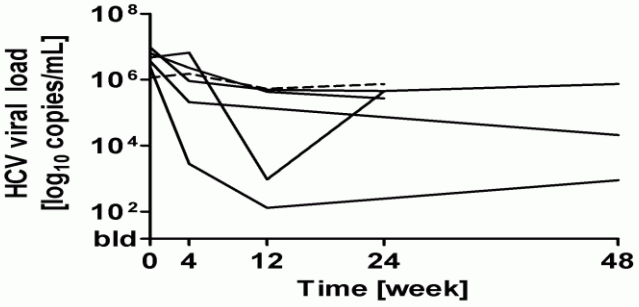
Background: Despite the availability of first generation protease-inhibitors (PI) against hepatitis C virus (HCV), treatment success remains limited in HIV-HCV co-infected individuals with advanced liver fibrosis and nonresponse to previous pegylated interferon and ribavirin (PR). We investigated the efficacy and tolerability of a lead-in therapy with intravenous Silibinin (iSIL) prior to triple therapy (TT) in this most difficult-to-treat population.

Methodology: Inclusion criteria were advanced liver fibrosis and a documented null or partial response to previous PR (Figure part A). Intervention was a lead-in therapy with iSIL 20mg/kg/day for 14 days. Subsequently, TT (PR and telaprevir) was initiated for the duration of 12 weeks and PR alone continued until week 48. Outcome measurement was HCV-RNA after two weeks of iSIL lead-in, at week 2, 4 and 12 of TT and end of treatment response (ETR) at week 48. Sustained virologic response data week 24 for this study population is not yet available.

Results: We included six HIV-HCV co-infected individuals (5 men). Median age was 49 years (range 38-56). For 5 individuals the transmission mode was intravenous drug use. Genotype 1A, which is associated with poorer response to TT, was most prevalent (5/6) and all had a fibrosis grade METAVIR F3. All were under successful antiretroviral treatment (HIV-RNA <20c/ml) with a median $CD4^+$ cell count of 574/µl (range 175-686). Mean HCV-RNA decline under iSIL therapy was 2.6$\log_{10}$ copies/ml (range 2-3). Five of 6 individuals were virologically suppressed at week 2 and 4, and 6/6 at week 12. One individual had a breakthrough thereafter. At the end of treatment 5/6 individuals had undetectable HCV-RNA (Figure part B). Tolerability of iSIL was excellent without any serious adverse events.

Conclusion: Lead-in therapy with intravenous Silibinin prior to triple therapy was well tolerated and resulted in a rapid virologic decline and end of treatment response in 5 of 6 individuals. Intravenous Silibinin may increase the probability of HCV treatment success in this most-difficult-to treat HIV-HCV co-infected population with advanced liver fibrosis and non-response to previous pegylated interferon and ribavirin.

A:
Previous treatment failure in six HIV-HCV co-infected individuals with pegylated interferon and ribavirin dual therapy. The dotted line indicates the failing patient below.



B:
HCV viral load in the same six individuals during lead-in therapy with intravenous Silibinin for 14 days followed by triple therapy. bld: below level of detection, ETR: end of treatment response, PR: pegylated interferon and ribavirin