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[PL13.1] THE PRESCO TRIAL: ROLE OF EXTENDED DURATION OF THERAPY WITH PEGYLATED INTERFERON ALFA-2A PLUS WEIGHT-BASED RIBAVIRIN DOSE IN 389 HCV/HIV CO-INFECTED PATIENTS

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PURPOSE OF THE STUDY: The treatment of chronic hepatitis C has become a priority in HIV+ patients. The poorer therapeutic response in coinfecting patients compared to HCV-monoinfected individuals could be due to the use of low flat (800 mg/day) ribavirin (RBV) doses and/or short lengths of therapy in prior trials.

METHODS: In a prospective, multicenter, open, comparative trial, coinfecting patients with CD4 >300 cells/ μ l and elevated aminotransferases who had not previously been exposed to interferon received pegylated interferon alfa-2a (180 μ g per week) plus RBV (1000 mg daily if body weight <75 Kg; 1200 mg daily if >75 kg). Patients with HCV genotypes 1 and 4 were treated for 48 or 72 weeks, while patients with HCV genotypes 2 and 3 were treated for 24 or 48 weeks.

SUMMARY OF RESULTS: Out of 389 patients included in the trial, 61% were infected by HCV-1/4 and 67% had serum HCV-RNA >500,000 IU/ml. In an intent-to-treat analysis, sustained virological response (SVR) was achieved by 49.6%, significantly higher in 152 HCV-2/3 than 237 HCV-1/4 patients (72.4% vs 35%; $p < 0.0001$). Furthermore, the SVR was higher in patients allocated to extended versus shorten treatment arms (53% vs 31% for HCV-1/4 and 82% vs 67% for HCV-2/3), although a high drop-out rate in the former precluded to obtain definitive conclusions. Premature treatment

discontinuations due to serious adverse events occurred in 8.5% of patients. Infection with HCV-2/3, lower baseline HCV-RNA, and HCV-RNA <50 IU/ml at week 12 were independent predictors of SVR in the multivariate analysis.

CONCLUSIONS: PRESCO is the largest trial conducted so far in coinfecting patients using pegIFN plus RBV. The use of 1000-1200 mg/day of RBV was relatively safe and provided SVR in nearly half of HCV/HIV-coinfecting patients, twice higher in HCV-2/3 than HCV-1/4 carriers. Both the use of higher RBV doses and extended duration of therapy most likely explained the better responses in this study compared to prior trials conducted in coinfecting patients.

Plenary Session: Hot Topics and Late Breakers

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