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HCV relapse after peg-interferon (IFN) plus ribavirin (RBV) therapy: is 12-week follow-up enough to determine sustained HCV clearance?

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Background

Sustained HCV clearance after pegIFN-RBV is less frequent in HIV-positive (-pos) than in HIV-negative (-neg) individuals. Less information exists about the rate of HCV relapses and timing for recurrence of HCV viremia upon completion of therapy in these two populations.

Methods

Retrospective analysis of all IFN-naïve patients with chronic hepatitis C who received a full course of 48 weeks of pegIFN (alpha 2a or 2b, at standard doses) plus weight-adjusted RBV (~13 mg/kg, 1,000–1,200 mg/day) therapy and had negative serum HCV-RNA at the end of treatment (EOT). Incidence and timing for HCV relapse were analyzed separately in HIV-pos and HIV-neg patients. Serum HCV-RNA was measured at EOT and every 3 months thereafter during the next year using a real-time PCR assay (Cobas Taqman, Roche), which has a lower limit of detection of 10 IU/mL.

Summary of results

A total of 610 patients treated with pegIFN-RBV were retrospectively identified; 390 (64%) HIV-pos and 220 (36%) HIV-neg. A total of 253 (41%) patients achieved EOT response (ITT analysis); 152 HIV-pos (39%) and 101 HIV-neg (46%) patients (p = 0.03). At EOT, main differences between HIV-pos vs. HIV-neg patients were as follows: mean age (41 vs. 45 years-old, p < 0.01), male gender (70% vs. 55%, p = 0.01) and HCV genotype 1–4

(58% vs. 79%, p < 0.01). HCV relapse occurred in 49 (32%) HIV-pos and in 26 (26%) HIV-neg subjects (p = 0.5). Timing for relapse was comparable in HIV-pos and HIV-neg patients: 70% vs. 55% within 12 weeks following EOT; 27% vs. 40% between week 12 and 24 following EOT, respectively (p = 0.3). There were two patients (one HIV-pos and one HIV-neg), who relapsed after week 24 following EOT. Re-infection was excluded in both cases by phylogenetic analysis. HCV genotype influenced the rate of relapse (more frequent in HCV-1/4 than in HCV-2/3), but not timing for relapse.

Conclusion

While the proportion of patients achieving EOT is lower in HIV-pos than HIV-neg, subsequent relapse occurs with similar frequency in the two groups (~30%). The rate of late relapses (≥week 12 upon completion of therapy) with pegIFN-RBV is greater than formerly reported using IFN monotherapy (2%, Zeuzem et al., J Hepatol 2003), regardless of HIV status. The use of RBV may not only reduce the risk for relapse (Shiffman et al., Hepatology 2007) but also delay timing for relapses upon completion of hepatitis C therapy. Therefore, 24 weeks of follow-up following EOT are warranted to ensure the achievement of sustained HCV clearance in most cases.