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Pegylated Interferon-alpha-2a Plus Ribavirin for Treatment-naive Asian Patients with Hepatitis C Virus Genotype 1 Infection: A Multicenter, Randomized Controlled Trial.

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BACKGROUND: Comparable sustained virologic response (SVR) rates have been documented between Asian patients who received 24 weeks of pegylated interferon (IFN) plus ribavirin and white patients who received 48 weeks of combination therapy for hepatitis C virus genotype 1 (HCV-1) infection. Whether a 48-week course of combination therapy shows a better SVR rate than a 24-week course of such therapy among Asian patients with HCV-1 infection has not been confirmed in multicenter, randomized studies.

METHODS: In this multicenter, randomized trial, 308 treatment-naive HCV-1-infected Asian patients were randomly assigned to receive either 24 or 48 weeks of pegylated IFN-alpha-2a (180 microg per week) plus ribavirin (1000-1200 mg/day) therapy. The primary end point was SVR, defined as an undetectable serum HCV RNA level 24 weeks after discontinuation of therapy. In addition, rapid virologic response (RVR) was defined as an undetectable serum HCV RNA level at week 4 of therapy, and complete early virologic response was defined as an undetectable serum HCV RNA level at 12 weeks of therapy in the absence of RVR.

RESULTS: By intention-to-treat analysis, patients who received 48 weeks of therapy had a significantly higher SVR rate than did those who received 24 weeks of therapy (76% vs. 56%; P < .001). Among patients with a baseline serum HCV RNA level <800,000 IU/mL and RVR, SVR rates were comparable between 24- and 48-week courses of therapy (94% vs. 100%; P = .13). In contrast, 48 weeks of therapy was associated with a significantly higher SVR rate than was 24 weeks of therapy among patients without RVR (39% vs.16%; P = .01) and among those who achieved a complete early virologic response (44% vs. 20%; P = .02).

CONCLUSIONS: In treatment-naive Asian patients with HCV-1 infection, 48 weeks of pegylated IFN-alpha-2a plus ribavirin therapy is associated with a higher SVR rate, compared with 24 weeks of such therapy. Patients with a baseline serum HCV RNA level <800,000 IU/mL and who have achieved an RVR can receive a 24-week course of therapy without compromising the SVR rates; however, those who have not achieved an RVR but who have achieved a complete early virologic response should receive a 48-week course of therapy.
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