HCV-related advanced fibrosis/cirrhosis: randomized controlled trial of pegylated interferon alpha-2a and ribavirin

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In patients with hepatitis C virus (HCV)-related advanced fibrosis/cirrhosis, 30% of sustained HCV clearance has been reported with pegylated interferon alpha-2a (PEG-IFN) alone, but the efficacy and tolerability of the PEG-IFN/ribavirin (RBV) combination remain poorly defined. A total of 124 treatment-naïve patients with biopsy proved HCV-related advanced fibrosis/cirrhosis (Ishak score F4-F6, Child-Pugh score < or =7) were randomized to 48 weeks of PEG-IFN (180 microg sc weekly) and standard dose of RBV (1000/1200 mg po daily, STD) or PEG-IFN (180 microg sc weekly) and low-dose of RBV (600/800 mg po daily, LOW). Sustained virologic response (SVR) rates with PEG-IFN/STD RBV (52%) were higher--albeit not significantly--than that with PEG-IFN/LOW RBV (38%, P = 0.153). In multivariate analysis, genotype 2/3 and a baseline platelet count > or =150 x 10(9)/L were independently associated with SVR. The likelihood of SVR was < 7% if viraemia had not declined by > or =2 log or to undetectable levels after 12 weeks. Nine adverse events in the STD RBV and 15 in the LOW RBV group were classified as severe (including two deaths); dose reductions for intolerance were required in 78% and 57% (P = 0.013), and treatment was terminated early in 23% and 27% of patients (P = n.s.). The benefit/risk ratio of treating compensated HCV-cirrhotics with STD PEG-IFN/RBV is favourable.

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