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Efficacy of The Novel Pegylated Interferon alfa-2a Derived from Hansenula polymorpha, Ribavirin and Amantadine combination in Treatment of Egyptian Patients with Chronic Hepatitis C Genotype 4: Randomized Trial.

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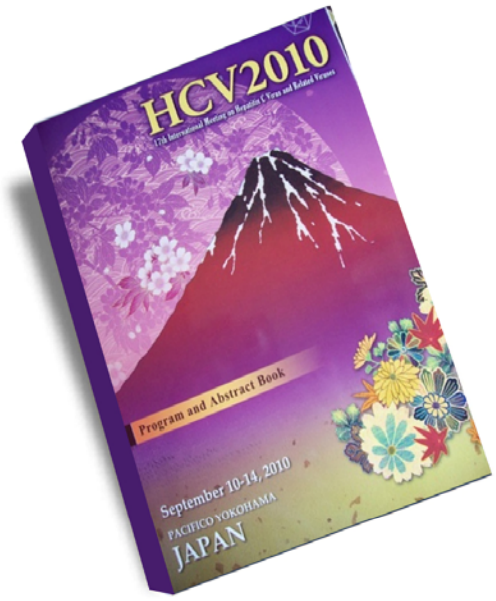
Rationale and Background:

HCV is the leading cause of liver disease in Egypt. Genotype 4 is the commonest genotype among Egyptian patients. A novel pegylated interferon alfa-2a derived from Hansenula polymorpha was introduced in Egypt since 2007. The aim of this work was to study the efficacy and safety of the novel 20-kD pegylated interferon alfa-2a derived from Hansenula polymorpha in combination with ribavirin and amantadine sulfate in the treatment of Egyptian patients with chronic hepatitis C (CHC) genotype 4.

Rationale and Background::

One hundred and twenty four patients with CHC genotype 4 were involved in this study. Liver biopsy was performed in all patients. Patients were randomized into 2 groups: Group I which included 63 patients who received fixed weekly dose of 160 ug of the novel pegylated interferon in combination with ribavirin in standard and adjusted doses. Group II included 61 patients who received amantadine sulfate 100 mg twice daily orally in addition to the regimen of group I patients. Serum HCV RNA was assessed by a real time sensitive PCR at 4, 12, 48 and 72 weeks from the start of therapy. Early virological responders (EVR) completed a 48 week course of treatment.



17th International Meeting on Hepatitis C Virus & Related Viruses Yokohama-Japan, 2010.

Results:

Sustained virological response (SVR) was (58.73%) in group I and (63.93%) in group II and this difference was statistically insignificant (p=0.552). The SVR was significantly higher in patients with low degree of liver fibrosis by Metavir score (F1 & F2) in groups I and II compared to those with high degree of liver fibrosis (F3 & F4) (69.77% versus 33%, p=0.004 in group I; 75% versus 45%, p=0.026 in group II). The distribution of patients with low degree of liver fibrosis was statistically indifferent in both groups (66.66% in group I, 65.57% in group II; p=0.898).SVR was significantly higher in patients who achieved rapid virological response (RVR) than those who could not achieve RVR in both groups (92.31% versus 50%, p=0.006 in group I; 91.67% versus 57.14%, p=0.026 in group II). The baseline viral load had no impact on SVR in both groups. No serious adverse events were reported in this study.

Conclusion:

The novel pegylated interferon alfa-2a derived from Hansenula polymorpha is effective in the treatment of CHC genotype 4 patients and is safe and well tolerated. Amantadine sulfate is not effective in increasing the SVR significantly in these patients. Low degree of liver fibrosis by Metavir score (F1 &F2) is a pretreatment predictor of response to treatment while RVR is an intra-treatment predictor of response.