

# NEWSLETTER INTERNATIONAL PUBLICATIONS

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## Predictive Value of Pretreatment Liver Histology and Viral Kinetics on Sustained Virological Response in HCV Patients treated with Hansenula-derived Pegylated Interferon Alpha-2a 160 µg with Ribavirin

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### INTRODUCTION:

Egypt has the highest worldwide prevalence of HCV, with 9% countrywide and up to 50% in certain rural areas, due to specific modes of infection. The currently recommended therapy of chronic HCV infection is the combination of a Pegylated Interferon and Ribavirin.

### AIMS:

The aim of this work was to evaluate the Predictive Value of pretreatment viral load & stage of fibrosis on the sustained virological response (defined as the absence of HCV RNA from serum 24 weeks following discontinuation of therapy).

### METHODS:

An open label trial where 127 Egyptian chronic hepatitis C patients received a weekly fixed dose of 160 µg PEG-IFN alpha-2a (Reiferon Retard®) plus weight adjusted dose of Ribavirin (11-13 mg/kg/day) for 48 weeks. Patients who responded at week 12, early virological response (EVR), completed a 48 weeks course of treatment. HCV RNA was assessed by Real time PCR at pretreatment & weeks 12, 24, 48 during treatment, and at week 24 of follow-up. Pretreatment liver biopsy was done to evaluate the stage and grade of liver fibrosis.

### RESULTS:

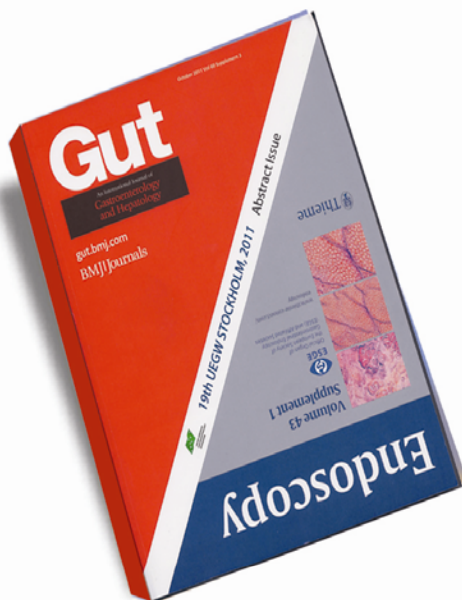
Overall sustained virological response (SVR) was 63.8% (81 patients out of 127). SVR was higher in patients with low degree of liver fibrosis by ISHAK score (F1 & F2) (73.2%) compared to those with high degree (F3, F4 & F5) (51.7%). Patients with pretreatment viral load ≤600,000 IU/mL achieved SVR of 68.9% (62 out of 90 patients) versus 51.4% (19 out of 37 patients) for patients with viral load >600,000 IU/mL. No serious side effects or drug discontinuation were reported.

Prediction Factor	No. of Patients	EVR*	ETR*	SVR*
<b>Fibrosis Score</b>				
Low (F1 & F2)	71	87.3% (62/71)	76.1% (54/71)	73.2% (52/71)
High (F3, F4 & F5)	56	78.6% (44/56)	57.1% (32/56)	51.7% (29/56)
<b>Viral Load</b>				
Low (≤600,000 IU/ml)	90	84.4% (76/90)	73.3% (66/90)	68.9% (62/90)
High (>600,000 IU/ml)	37	81.1% (30/37)	54.1% (20/37)	51.4% (19/37)

\*EVR: Early Virological Response. \*ETR: End of Treatment Response. \*SVR: Sustained Virological Response.

### CONCLUSION:

Patients with low fibrosis stage & pretreatment viral load ≤600,000 IU/mL achieved a higher SVR when compared to patients with higher fibrosis grades & higher viral load when treated with hansenula-derived pegylated interferon alpha-2a, in combination with Ribavirin.



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