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Failure of Nitazoxanide to Improve Response of Hepatitis C Patients to Pegylated Interferon and Ribavirin Therapy

Prof. I. WAKED[1], *Dr. A. SABRY*[1], *Dr. E. EL-SHIMI*[1], *Dr. O. AL-HADDAD*[1], *Prof. H. EL-SAEED*[2], *and Dr. H. TAHA*[1]

1.Hepatology,
2.1.Biochemistry,
National Liver Institute, Shebeen El-Kom, Egypt.

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INTRODUCTION:

Several reports indicated that the synthetic anti-protozoal nitazoxanide (NTZ) given for 12 weeks lead-in and in combination with pegylated interferon (PEG-IFN)-ribavirin (RBV) improves response of patients with hepatitis C to antiviral therapy. In this trial we compared 2 regimens of triple therapy of NTZ – PEG-IFN – RBV to standard treatment with PEG-IFN – RBV for 48 weeks in Egyptian patients with hepatitis C.

PATIENTS and METHODS:

125 Patients with chronic hepatitis C without cirrhosis (mean age 35.6, 39% female) were randomized to receive NTZ 500 mg b.i.d. for 4 weeks (n=50) or 12 weeks (n=50) before combination therapy with PEG-IFN (a bio-similar 20 kD PEG-IFN alpha 2-a 160 µg/week- Reiferon Retard®) and weight-based RBV for 48 weeks; or standard therapy PEG-IFN – RBV for 48 weeks (n=25).

RESULTS:

Viremia increased during the lead-in period in both groups (HCV-RNA increased from 689×10^3 to 999×10^3 IU/ml in the 4 weeks lead-in group, and from 530×10^3 to 701×10^3 IU/ml in the 12 weeks lead-in group). 65 Patients in the 3 groups (52%) achieved sustained virological response (SVR). The results during different periods of the study are shown in the table. Adverse events were not increased with addition of NTZ, and only one patient discontinued therapy during the lead-in period due to continuous allergic reaction. Addition of NTZ did not result in increase in response in either group, and the SVR was higher with standard treatment than with the addition of NTZ with either lead-in duration (p=0.185).

	SOC (n=25)	NTZ 4 weeks lead-in (n=50)	NTZ 12 weeks lead-in (n=50)
RVR	42%	40%	34%
EVR	72%	60%	62%
ETR	68%	60%	50%
SVR	68%	50%	46%

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

CONCLUSION:

The lead-in phase of the study showed that NTZ had no beneficial effect on viremia, and the addition of NTZ did not increase response to PEG-IFN – RBV therapy in this group of Egyptian patients with chronic hepatitis C.