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Efficacy and clinical response to Reiferon Retard® in patients with chronic hepatitis C in Egypt.

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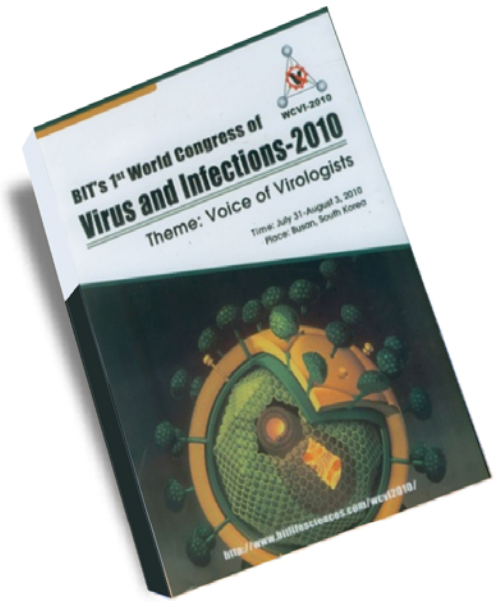
Introduction and background:

HCV infection leads to chronic hepatitis in approximately 80% of infected subjects. About 10-30% of those with chronic HCV develop cirrhosis over a course of 10-20 years. HCV is a family of viruses for which six main genotypes have been described. Genotype 4 is the most prevalent genotype described in Egypt (~ 90%). Treatment of HCV infection not only prevents hepatic complications but also prevents spread the of infection among population with high prevalence rate like Egypt. Data from Egypt showing initial response rate to combined Interferon/Ribavirin therapy is around 50-60%, which probably ends as 40-45% sustained response rate.

Subjects and methods:

A novel patent 20 KD Peg-IFN alpha 2a (Reiferon Retard®) expressed in yeast Hansenula polymorpha was evaluated in 70 naïve chronic HCV Egyptian patients. During the study, we have evaluated the efficacy and validity of the Reiferon Retard® by INF-EIA specific assay. To ensure the viral clearance and avoid false negative results, we have tested each sample by 4 different assays; RT-PCR in sera and PBMC, Real time and TMA. The 70 patients were classified by Metavir score into 2 groups. Group 1(F ≤ 1-2,n= 58) and Group 2 (F ≥ 3,n=12). We have assessed all patients clinically and all laboratory assays were evaluated at 0, 4, 12, 24, 48 and 72 weeks. Sequence analysis is now being done to distinguish genotype 4.



BIT's 1st World Congress
of Virus and Infections
Busan -South Korea, 2010.

Results: and Conclusion

Tracing a single dose Reiferon Retard® could be detected in patients till the 5-6th days after injection. There are no major side effects and patients continued the study till the end of follow up at 72 weeks. The end of treatment showed that Group 1patients (F ≤1-2) response rate was 63.2% and Group 2 patients (F ≥ 3) response rate was 33.3%. The overall sustained viral response (SVR) at 72 weeks showed 50% response at which Group 1patients (F ≤1-2) had better SVR of 55% (32 out of 58 patients) while Group 2 patients (F ≥ 3) had 25% (3 out of 12 patients). The SVR of genotype 4 will be determined after obtaining the sequence analysis results. We concluded that the new molecule of Reiferon Retard® is safe and has comparable efficacy to other INFs available commercially.