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Effect of Sofosbuvir, brand drug (Sovaldi) versus generic (MPIViropack) in treating Chronic HCV infection among Egyptian patients

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Sofosbuvir is a NS5B polymerase inhibitor with effective pan-genotypic coverage and approved for use in genotype IV. With the availability of both the brand drug (Sovaldi- Gilead) and the generic form (MPI-Viropack- Marcyrl Pharmaceutical Industries) in the Egypt, we conducted this comparative study to evaluate and compare the safety and efficacy of both forms. In this study we recruited 105 patients with chronic HCV infection. For all of them the following was done: Liver function tests (S. bilirubin, ALT, AST, Albumin, PT and PC), CBS, ECG, Fundus examination, Abdominal ultrasound, Fibroscan and HCV RNA Quantitative by PCR. They were divided into three groups, 35 patients each. According to Fibroscan, in the first group, 23 patients had F2, 9 patients F3 and 3 patients F4 and the second group showed F2 in 22 patients, F3 in 10 patients and F4 in 3 patients, and the third group showed 22 patients with F2, 6 patients with F3 and 7 patients with F4. For the first group, triple therapy was used, Peg Interferon (Peg Intron- MSD according to body weight), Ribavirin in a weight adjusted dosage and Sovaldi- Gilead 400 mg once daily. For the second group, triple therapy was also used, Peg Interferon and Ribavirin as in group I and MPIviropack 400 mg once daily. For the third group, dual therapy was given using Ribavirin in a weight adjusted dosage and either Sovaldi 400 mg once daily (17 patients) or MPIviropack once daily (18 patients). Follow – up after one and three months using liver function tests, CBC and HCV RNA by PCR was done. There was normalization of liver enzymes in 34 (97%) patients group I and II, and 35 patients (100%) in the third group. CBC showed mild decrease in HB level in 18, 19, 15 patients in group I, II, III respectively. HCV RNA was not detected in 34 (97%) patients in group I, II and III. The side effects were comparable in group I and II: Nausea and abdominal Pain in 20 (57%) patients in Gr. I versus 21 (60%) in Gr. II, diarrhea in 3 (8.5%) patients in Gr. I versus 4 (11.4%) patients in Gr. II, headache in 4 (11.4%) patients in both groups. However in Group III the side effects were mild including asthenia in 20 (57%) patients and mild gastric upset in 15 (43%) patients. Follow-up is still going on to assess the SVR 12, 24 in group I and II and till the end of treatment for 6 months in group III and till we get their SVR 12, 24. From this pilot study, we found that both the brand and the generic forms of Sofosbuvir in combination with Peg/R or with Ribavirin alone proved safe and effective in Egyptian patients with chronic HCV – genotype 4 with comparable safety and efficacy profile. The long term follow-up to assess the SVR in 12, 24 weeks are still going on.

Biography

Hosny Salama is currently working as a Professor of Hepatology and Tropical Medicine at Cairo University, Egypt. He is the President of Egyptian Society for study of Updates in Hepatology and Gastroenterology and Egyptian Society of Stem Cell Therapy. He also published many papers in national and international peer-reviewed journals.

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