Evaluation of the efficacy of the combination of generic sofosbuvir plus daclatasvir, with or without ribavirin, in 3079 patients with hepatitis C: Egyptian Social Security Cohort

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- Context: The effectiveness of the combination of sofosbuvir (SOF) and daclatasvir (DCV) with or without ribavirin (RBV). has been demonstrated in several clinical trials. A large cohort was treated, using generics, as part of the Egyptian Social Security hepatitis C elimination program.
- Objective: to evaluate the efficacy of the generic combination SOF-DCV, with or without RBV, and to evaluate the predictive factors of response.
- Methods: Cohort study of patients with chronic HCV treated in a specific center of Social Security (Cairo). Patients received 12 weeks of combination therapy with SOF (400 mg / day) and DCV (60 mg / day) with or without RBV (600 mg / day). Patients were classified as difficult to treat (group I) or easy to treat (group II). Patients who were difficult to treat were either non responders to previous interferon-based therapy or had one or more of the following criteria: bilirubin> 1.2 mg / dl, albumin ≤3.5 mg / dl, INR≥1, 2, platelets≤150,000 / mm3. Only group I patients received RBV. Efficacy was assessed as well as factors associated with no sustained virologic response (undetectable HCV RNA 12 week's post-treatment, RVS12).
- Results: from November 2017 to September 2018, out of 3541 patients seen at the Social Security Center in Cairo, 386 were excluded according to the Egyptian protocol for the care of HCV; 76 patients were excluded due to co-infection with HBV. A total of 3079 patients were (group I, 1456 patients, 47.3%, group II, 1623 patients, 52.7%). Patients in groups I and II had an average age of 55.6 ± 11.7 and 56.3 ± 11.7 years respectively with a proportion of men of 78.1% and 76.2%. SVR12 was observed in 95.1% of patients included (94.5% of group I and 95.7% of group II, NS). Non-responder patients (no SVR12) had lower hemoglobin and platelets, lower INR, higher ASAT, and higher viral load (HCV RNA).
- Conclusion: This study shows a high (95%) sustained virological response (SVR12) with the combination of generic SOF-DCV with or without ribavirin suggesting equivalent efficacy of generics. The results were not different in "difficult" and "easy" to treat patients , although the majority of "difficult" patients probably had more advanced fibrosis or cirrhosis. These results confirm that the addition of ribavirin is useful in these patients. The favorable results obtained in this Social Security study prompted the Egyptian government to launch the massive national campaign to eliminate hepatitis C using this antiviral combination.