Safety and Efficacy of Sofosbuvir plus Ledipasvir Combination in Treatment of Chronic Hepatitis C Infection in School Age Patients (12-17 years old)

Thesis
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Summary

HCV is a blood-borne virus responsible for both high morbidity and mortality rates worldwide with significant indirect costs so HCV is being considered as a major public health threat.

DAAs with their low-cost and high efficacy helped in treating millions of HCV infected patients worldwide**.**

WHO released a document in 2016 about its future global vision to eliminate viral hepatitis as a major public health threat by 2030.

The main attention of the global response was on the diagnosis and treatment of adults, who have the major burden of morbidity and mortality of CLD related to HCV. When compared with adults, there has been much less attention to management of HCV in children and adolescents.

In this study we aimed to evaluate the safety and efficacy of SOF plus LDV combination in treatment of CHC infected adolescent patients aged from 12 to 17 years old.

This cohort study was conducted on 147 Egyptian adolescent patients with CHC who were treated with SOF 400 mg and LED 90 mg combination at Fayoum insurance hospital according to the national program for treatment of HCV in Egypt.

The mean age of the study group was (15.46 ± 1.74) years old and 61.2 % of them are males. Regarding the mode of HCV transmission; 39.5% were possibly

infected through vertical transmission, 28.6% through horizontal transmission, 7.5% through both vertical and horizontal routes and 24.5% are of unknown source of infection.

When reviewing baseline investigations of the study group, there was mild elevation of mean ALT level which had no correlation to the level of HCV viremia, mean FIB-4 and APRI scores before treatment were 0.34 & 0.36 respectively. As regards abdominal US findings; 51% had normal findings, 46.9% had bright liver and 2% had hepatomegaly.

Our study showed that SOF-LED regimen had a high rate of SVR (99.3%) in this group of patients, only one patient didn't achieve SVR as he was not adherent to treatment. The regimen was well tolerated, with no discontinuation related to intolerability has been reported. Most importantly, side effects were minimal; 71.4% of our patients didn`t report any side effects related to the treatment, others reported headache, fatigue or both of them. Fatigue was the main side effect being reported in about 16.3% of the patients.

This study showed normalization of ALT and AST levels after treatment denoting regression of inflammation of the liver. Also FIB-4 and APRI scores follow up 2 years after SVR statistically significantly decreased in comparison to their levels before treatment **(0.34 & 0.36) to (0.25 & 0.17)** respectively.

Finally, main Hb level statistically significantly decreased during and after treatment in comparison to its level before treatment and main PLT count statistically significantly increased after treatment in comparison to its level before and during treatment but of no clinical significance as all values are within normal range.

In conclusion, a 12-week regimen of SOF plus LED is well tolerated and associated with minimal adverse events and high SVR in adolescent patients with and can be safely used in this age group.

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