

# The effectiveness of oral antiviral (Sofosbuvir/ledipasvir) in treating children with HCV infection

Ban Adil Al-Kaaby

Zagazig University, Egypt E-mail: [banalkaaby@uomustansiriyah.edu.iq](mailto:banalkaaby@uomustansiriyah.edu.iq)

## Abstract

**Objectives:** to work out the efficacy of (Sofosbuvir/ledipasvir) in treating children with HCV infection. **Patients and methods:** Patients with positive HCV PCR, aged 7 to 18 years were enrolled. History and clinical examinations and investigations were conducted. HCV genotyping was done (if affordable). Sofosbuvir was given to all or any patients once daily. Ribavirin was added for INF-experienced patients or with established cirrhosis. Follow up with liver function and renal function and PCR was done at 12 weeks (end of treatment); then after 12 weeks post treatment (SVR12). Total duration of therapy was 12 weeks. Extended to 24 in cases with established cirrhosis. **trojan horse SPSS version 20** was used for data analysis. **Results:** the quantity of patients were 22, with mean age of 12.5 years, 14 boys (63.6%), and eight girls (36.4%). Genotype 1 was the dominant type (75%). SVR 12 was achieved in 20 patients (90.9%), the remaining 2 (9.1%) had partial virological response. HBV co-infection was found in 5 cases; they were kept on Entecavir during the course of treatment. All achieved SVR12 for HCV and reduce titer for HBV. Even INF-experienced patients (7 patients 31.8%) were responsive with SVR12. The treatment was well tolerated. **Conclusion:** Sofosbuvir/ledipasvir is effective in treating HCV in children, and is well tolerated. **Key word:** Direct acting antivirals, hepatitis C virus, Sofosbuvir/ledipasvir, Pediatrics, children.

HCV PCR positive patients mentioned the Gastroenterology, Hepatology Center /Pediatrics department and therefore the Central Child Teaching hospital, Baghdad / Iraq from April 2017 to January 2018 were interviewed. History, clinical examination and investigations were in hot water all enrolled patients. Complete blood count, total serum bilirubin, ALT, AST, alkaline phosphatase, abdominal ultrasound and HCV genotyping (if financially affordable by the patient). All patients were started on Sofosbuvir 400 mg/ledipasvir 90mg once daily. If patients were but 12 years, half the dose was given. 6 Ribavirin 10-15 mg/kg/day was added if patient was INF-experienced or had established cirrhosis. All the patients were followed with liver function and renal function test within the 4th week of treatment. PCR was done at 12 weeks (end of treatment); then after 12 weeks post treatment (SVR12). Total duration of

therapy was 12 weeks. Extended to 24 in cases with establish cirrhosis. **worm SPSS version 20** was used for data analysis. A total of twenty-two patients were included during this study, the mean age was 12.5 years the youngest patient received treatment was seven years old. there have been 14 boys (63.6%), and eight girls (36.4%). Genotype of the HCV was done by 12 (54.5%) patients only because of financial causes. Nine of them were genotype 1(75%) all were genotype 1a except one which was 1b. The remaining three cases (25%) were genotype 4. PCR level was high (more than one 800,000 IU/ml) 8 in 14 patients (63.6%), mean level 9,016,862 IU/ml, minimum level 4,871 IU/ml and maximum level 35,175,925 IU/ml. SGPT was elevated in 9 cases (40.9%). Cases referred from the Hematology and Oncology ward, with history of insertion were 20 cases (86.36%) (thalassemia, leukemia, Hodgkin's disease), one had a history of surgery, the opposite one had unknown source of infection. Seven patients (31.8%) had previously been treated with Interferon; four were non-responsive, while one couldn't tolerate the side effects namely leukopenia and thrombocytopenia.

The last two patients had developed autoimmune hepatitis during the course of treatment, for this reasons they were discontinued from the interferon regimen. most aside from one among the treatment-experienced patients were genotype 1 (86%), genotype 4 only 1 case (14%). Concomitant infection with HBV was found in 5 patients, they were concomitantly treated with Entecavir or Tenofovir during the course of treatment. Two cases from the sample had established hepatic cirrhosis, both had previous history of ALL (acute lymphoblastic leukemia), both of them had autoimmune hepatitis related to the HCV, one had received interferon for few months but stopped due to no response. End-of-treatment PCR was negative in 20 patients (90.9%), the remaining 2 (9.1%) had partial virological response. those that had associated autoimmune hepatitis with established cirrhosis were responsive with negative PCR after 24 weeks of treatment. Those with concomitant HBV infection, they responded well and every one had achieved negative PCV at the tip of treatment. people who were previously treated with INF, all achieved a negative HCV PCR at 12 weeks post treatment. The treatment

was well tolerated, one patient only complaint from headache. it absolutely was because of sinusitis that was treated and there was no treatment interruption. Hepatitis C virus (HCV) is one in all the main health problems world widely in spite of the advances in treating HCV in adult, data in paediatrics age groups are still limited. The new oral antiviral drugs have revolutionized the treatment of HCV everywhere the world. Since FDA approved the employment of (Ledipasvir and Sofosbuvir) in paediatrics age in April 2017, a brand new era in treating children with this disease has started. during this study, the youngest patient involved was six years, while another study in Pakistan had used it from five years old and above. The mean age of patients was 12.5 years. Male outnumbered female, the ration was about 2:1, same as in other study conducted in USA, UK, Canada.

In this study the mode of acquiring HCV was from blood or blood product transfusion in most of the cases. Contemporary literature shows that the vertical transmission is taken into account the most source of infection within the developed countries because of effective screening of donor blood that reduced the blood born infection, in USA as an example no more pediatric cases acquired HCV from blood born since 1994.<sup>10</sup> These findings are different from the developing countries where still the most source of infection blood born. Adding to it HCV was noticed to be significantly higher among patients who received repeated blood transfusion; about 67.3% in Iraq, 40% in Asian nation, 40.7% in Jordan, and 42.4% in Morocco. and most of our patients were referred from the hematological ward with history of blood and blood product transfusion.

**This work is partly presented at 13th International Conference on Pediatric Gastroenterology Hepatology & Nutrition**