Scientific research process

1 What did this study explore?

The study were designed to explore the efficacy and safety of SOF combined with DCV for HCV RNA-positive KT patients.

2 How did the authors perform all experiments?

This study enrolled a prospective cohort of consecutive Chinese KT patients with HCV infection. They were given SOF combined with DCV with or without RBV therapy. All patients were nonecirrhotic and naive to treatment, and their baseline eGFR is above 30 ml/min/1.73m^2. All patients received therapy for 12 wk. Clinical assessment, conventional liver and kidney biochemistry paremeters, serum HCV RNA, as well as the types of immunosuppressive drugs and their doses, were assessed routinely as follows: at the beginning of treatment; 2, 4 and 12 wk post-treatment; at the end of treatment (EOT); and at 12 wk after therapy was completed. Prothrombin time, alphafoetoprotein and abdominal ultrasonography were tested when necessary.

3 How did the authors process all experimental data?

Statistical analyses were performed by using SPSS 17.0 (SPSS, Chicago, IL). HCV RNA levels were logarithmically transformed for further analysis. Continuous variables were expressed as either mean ± standard deviation or as median and range. Frequencies were used for categorical variables. Quantitative variables were compared using the t test or the Mann-Whitney U test for variables according to different characteristics of distribution when necessary. Categorical data were compared using the Pearson $\chi 2$ test or Fisher's exact test when necessary. $P < 0.05$ (two-tailed) was considered statistically significant.

4 How did the authors deal with the pre-study hypothesis?

We reviewed a great deal of literature. We found the new-generation DAAs, (i.e., sofosbuvir (SOF) combined with daclatasvir (DCV), with or without ribavirin (RBV)) have been shown to be highly efficient in treating HCV infection in cirrhotic and noncirrhotic immunocompetent patients. However, limited data about efficacy and safety of direct-acting antiviral regiments (DAAs) in treatment of KT patients with HCV infection. So we conceived and designed the study.

5 What are the novel findings of this study?

Sofosbuvir plus Daclatasvir regimens is free of interferon. Our study showed that it is an safe, well-tolerated, efficacious and attractive option to treat HCV patients after kidney transplanationan.