EFECTIVENESS OF SOFOSBUVIR-BASED INTERFERON FREE-TREATMENT REGIMENS FOR CHRONIC HEPATITIS C VIRUS INFECTION

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BACKGROUND &PURPOSE

Interferon-free oral therapies have become elective treatment of chronic hepatitis C virus (HCV) infection, especially in cirrhotic patients. High rates of sustained virological response (SVR) have been reported but real-world data is required.

The aim of this study is to describe virologic response to sofosbuvir (SOF) – based interferon-free oral therapy in clinical practice.

MATERIALS & METHODS

Retrospective observational study of patients who initiated SOF-based therapy between May 2014 and March 2015.

Patients were treated with SOF-simeprevir (SMV) ± Ribavirin (RBV) for 12 weeks (12w) or SOF-daclatasvir (DCV)±RBV for 12 or 24 weeks (24w).

Demographic, pharmacological and microbiological data were collected.

Primary end point: SVR at 12w post treatment (SVR12).

Analysis was performed using SPSS v19.

RESULTS

100 patients were included (19 HIV coinfected patients). The baseline characteristics of our study population are described in Table 1.

- 80% of patients were genotype 1 (GT1): GT1a/1b: 20/60 (Figure 1)
- 86% had cirrhosis, 21% had previous liver transplantation.
- Prior therapy: 42 naïve, 14 relapsers, 44 non responders to IFN-based therapy.
- 66 % received SOF-SMV±RBV 12w (44% with RBV) and 34% SOF-DCV±RBV (79.5% for 24w. 17.6% with RBV) (Figure 2).

Baseline characteristics	Total (N=100)
Age, median (range)	56 (35-72)
Males, n	67
Genotype, n	
1 (1a/1b)	80 (20/60)
3	9
4	11
Baseline HCV RNA (IU/mL), Median (Q1-Q3)	534.854 (111.533- 2.2M)
Previous treatment status	
Naive, n	42
Relapser, n	14
Non-responder, n	44

Table 1. Patient Baseline Characteristics.

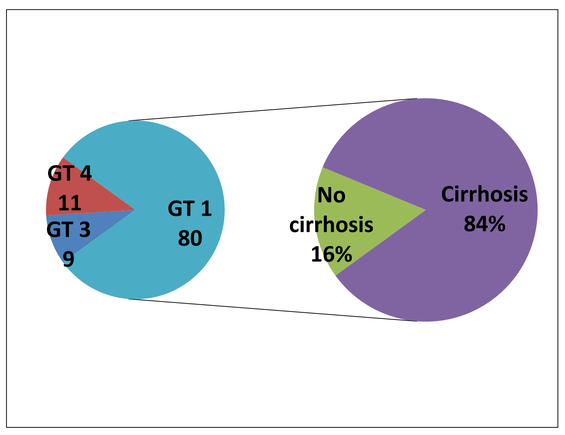

Figure 1. Genotype distribution. GT1: genotype 1, GT3: genotype 3, GT4: genotype 4

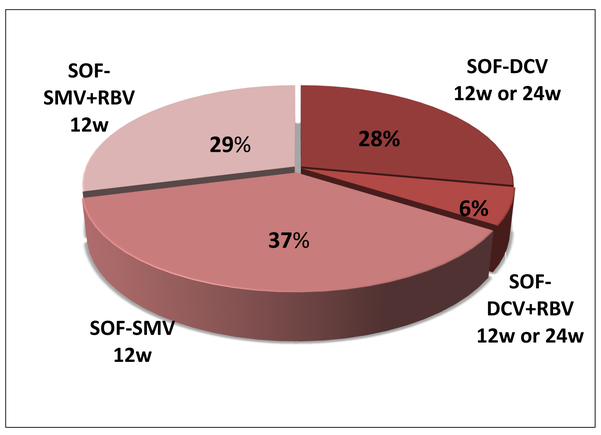

Figure 2. Treatment regimen. SOF: sofosbuvir. DCV: daclatasvir. SMV: simeprevir. RBV: ribavirin

- By week 4, 36% of patients were HCV RNA undetectable (Figure 3). In 48.4% of the patients who remained positive, HCV RNA was<30 IU/mL.
- Overall SVR12 rate: 85% (Figure 4)

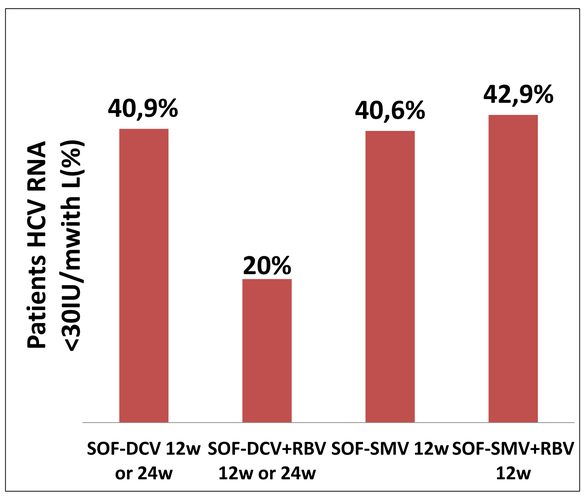

Figure 3. Viral response at week 4. SOF: sofosbuvir. DCV: daclatasvir. SMV: simeprevir. RBV: ribavirin

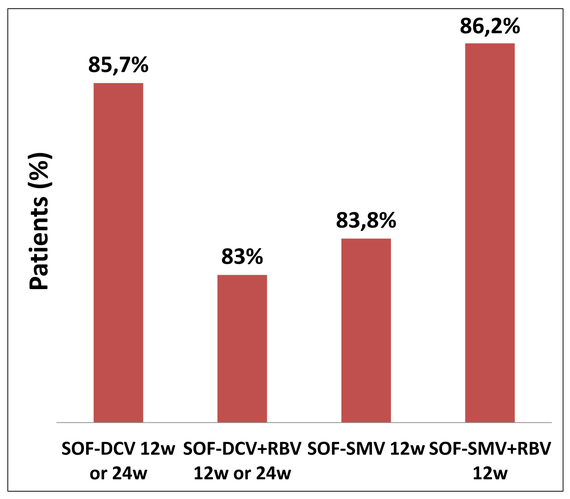

Figure 4. Sustained virological response at 12 weeks SOF: sofosbuvir. DCV: daclatasvir. SMV: simeprevir. RBV: ribavirin

GT1 cirrhotic patients

- 93% of GT1 cirrhotic patients achieved SVR12.
  - No statistically significant differences were found in SVR12 in these patients based upon:
    - HCV RNA at week 4 (<30 IU/ml *vs* >30 IU/ml: 96%/85%)
    - GT1a *vs* GT1b (93%/92.3%)
    - Antiviral therapy (SOF-SMV: 91.7%. SOF-SMV+RBV: 94.7%. SOF-DCV: 89.5%. SOF-DCV+RBV: 100%) (Figure 5)
    - Prior HCV treatment (naïve / treatment-experienced: 93% / 92%).
  - When RBV was not used, 24w of treatment improved SVR12 in GT1 cirrhotic patients receiving SOF-DCV (12w/24w: 33.3%/100%, p=0.018) (Figure 5).

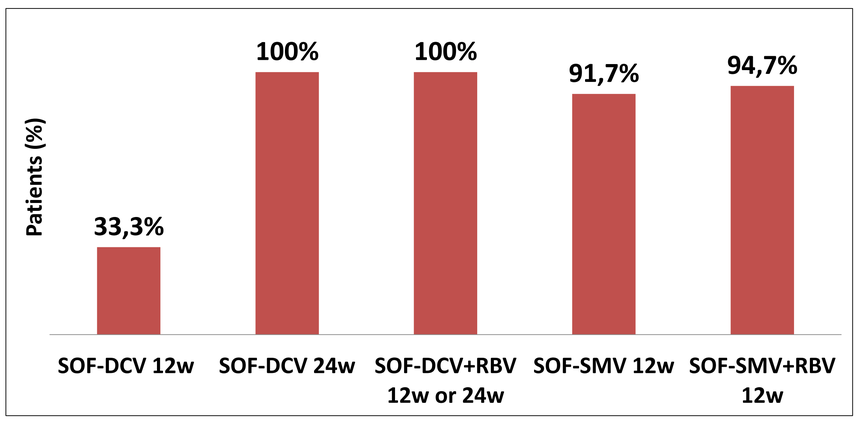

Figure 5. Sustained virological response at 12 weeks in genotype 1 cirrhotic patients.SOF: sofosbuvir. DCV: daclatasvir. SMV: simeprevir. RBV: ribavirin

CONCLUSIONS

- Combination sofosbuvir - simeprevir ± ribavirin and sofosbuvir - daclatasvir ± ribavirin are highly effective in patients with genotype 1 and cirrhosis.
- No statistically significant differences were found according to HCV RNA level at week 4 or prior HCV treatment.
- Cirrhotic genotype 1 patients receiving sofosbuvir - daclatasvir without ribavirin benefited from 24 weeks treatment duration but further studies are needed as sample size was small.

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