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BACKGROUND

New direct-acting antivirals (DAAs) for chronic hepatitis C have been developed. High rates of sustained virological response (SVR) have been reported. This represents an opportunity to eradicate hepatitis C virus (HCV) in these patients.

PURPOSE

To assess the effectiveness of the combination Sofosbuvir (SOF) and Ledipasvir (LDV) in HCV patients.

MATERIAL AND METHODS

Retrospective and observational study between April 2015 and January 2016. Inclusion criteria: Patients with HCV infection treated with SOF/LDV±Ribavirin (RBV) during study period. Exclusion Criteria: Patients with no data available.

Source of information

-Dispensing records saved on an outpatient software.
 - Medical records of patients.

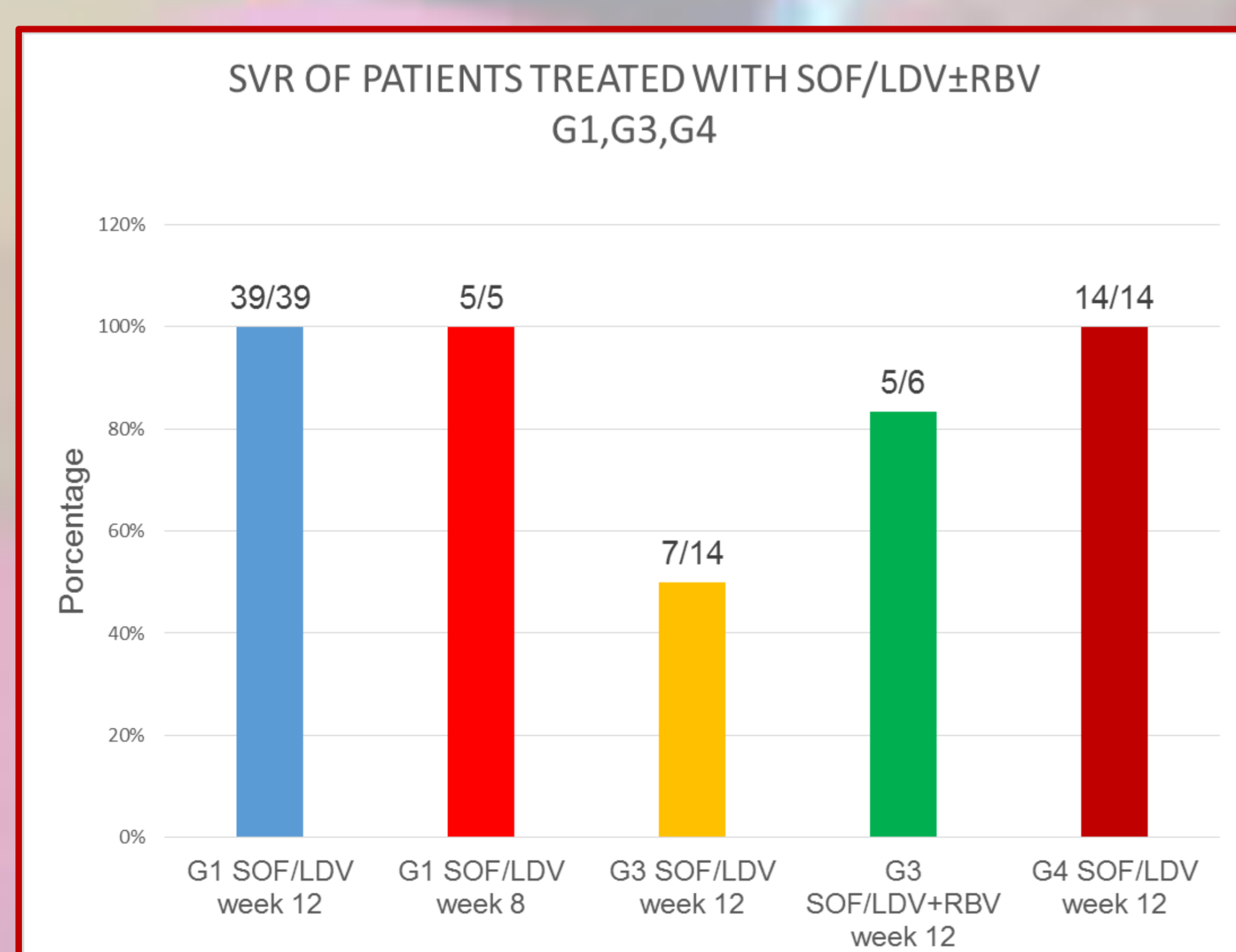
Variables analysed

- Demographics: age and sex.
 - Clinical data: viral load, sustained virological response (SVR12), METAVIR score F0-F4, liver transplant, HCV genotype, HIV co-infection, side effects.

Analysis of data collected: descriptive statistical analysis.

RESULTS

78 patients were included (71.79% men); mean age of 54,42±9,56 years. According to METAVIR score: F4 (cirrhosis) (37.18%), F3 (33.33%), F2 (23.08%), F1 (5.13%) and F0 (1.28%). The HCV genotype was: 56.41% G1, 25.64% G3 and 17.95% G4. 25 patients (32.05%) were HIV coinfectad. 16.66% had a liver transplant. 42.31% (33/78) had failed prior treatment, 81.81% were treated with peginterferon/RBV, 9.10% with peginterferon, 3.03% with RBV/peginterferon/protease inhibitor(PI), 3.03% with RBV/PI and 3.03% with simeprevir/SOF. According to basal VL, the 73% had a VL >800,000UI/ml.



Patients with G1 (N=44) treated with SOF/LDV 12 weeks (5 patients were treated only 8 weeks). All patients achieved SVR12 including one patient treated with SOF/LDV+RBV 12 weeks. Patients with G3 (n=20): treated with SOF/LDV 12 weeks (N=14) achieved SVR12→50% (N=7); treated with SOF/LDV+RBV 12 weeks (N=6) achieved SVR12→83.33% (N=5). Patients with G4 (N=14) were treated with SOF/LDV 12 weeks, all achieved SVR12. The treatment was well tolerated.

■ Patients with HCV genotype-1 infection treated during 12 weeks with SOF/LDV

■ Patients with HCV genotype-1 infection treated during 8 weeks with SOF/LDV

■ Patients with HCV genotype-3 infection treated during 12 weeks with SOF/LDV

■ Patients with HCV genotype-3 infection treated during 12 weeks with SOF/LDV+RBV

■ Patients with HCV genotype-4 infection treated during 12 weeks with SOF/LDV

CONCLUSION

The combination SOF/LDV±RBV was effective in non-responders and naive patients with HCV G1 and G4. The SVR12 rate achieved in our study confirms the results obtained in published clinical trials. According to G3, our results are slightly lower than those achieved in ELECTRON-2 trial; this could be due to treat only ten naive patients and four pretreated-patients with SOF/LDV without RBV.

ACKNOWLEDGEMENTS

No conflict of interest

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J05 - Antivirals for systemic use