Sofosbuvir in combination with simeprevir +/- ribavirin in genotype 4 hepatitis C patients with advanced fibrosis or cirrhosis: real-life experience from Belgium

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Background and aim

Efficacy and safety data of interferon-free regimens in hepatitis C (HCV) genotype 4(G4) patients are scarce. In Belgium, Sofosbuvir (SOF) and Simeprevir (SIM) treatment are available since January 2015 for G1 and G4 patients with advanced fibrosis (F3-F4 METAVIR) for 12 weeks.
The aim of the study was to evaluate the safety and efficacy of this treatment

Patients and Methods

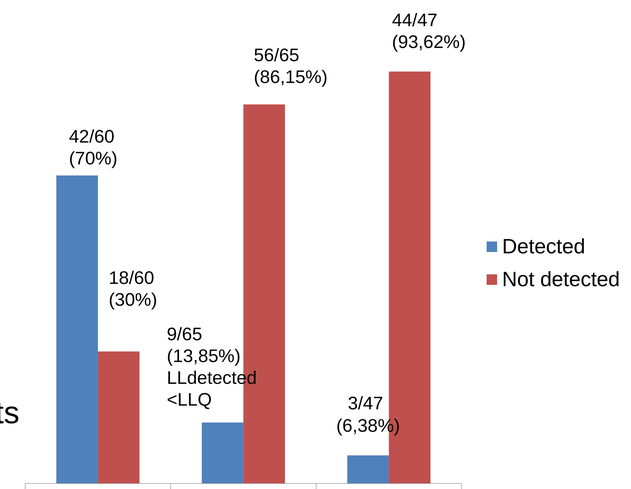
75 G4 patients were enrolled in this data collection including 41.3% with severe fibrosis (F3) and 58.7% cirhotic patients definied by histology or non invasive tests of liver fibrosis.

Results

1.Patients characteristics

	75 patients
Median age (years)	59 [30-81]
Male sex (%)	57,3
Treatment experienced patients (%)	77
F3/F4 (%)	41,3/58,7
Ribavirine treatment (%)	36
HIV coinfection (%)	10,5
Median ALT (UI/mL)	66[25-327]
Median bilirubine (mg/mL)	0,77 [0,10-5,70]
Median INR	1,1 [0,9-2,16]
Median platelet level (10^3/mm^3)	123 [23-320]
Albumin (g/L)	39,3 [24,5-58]
Ascites (cirrhosis) (%)	4,8
Encephalopathy (cirrhosis) (%)	2,5
MELD (cirrhosis)	9 [6-19]
Child-Pugh (cirrhosis)	5 [5-9]
Treatment duration 12W/24W	73/2

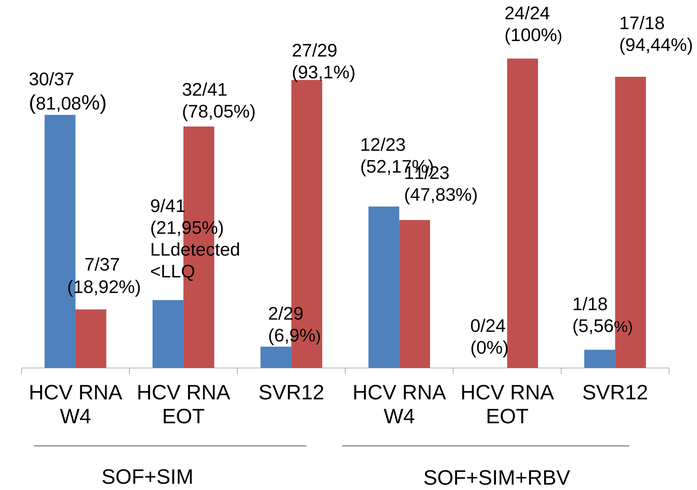
2. Virological response



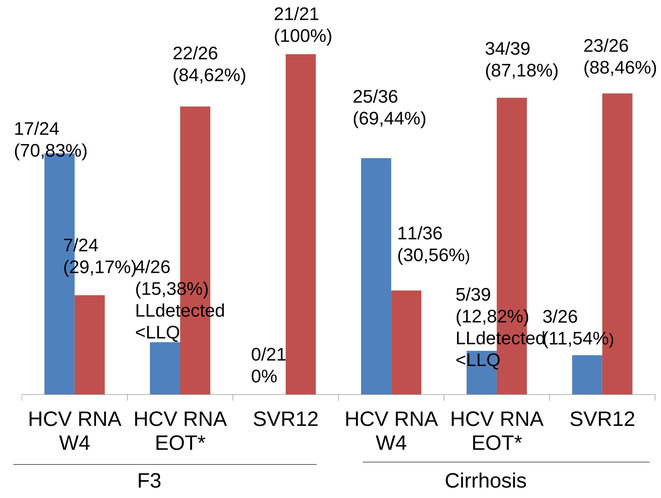
HCV RNA at week 4 of treatment, at the end of treatment (EOT) and at week12 after de end of treatment for all the population: Sustained virological response (SVR) 12: 93,6%

	Patient 1	**Patient 2**	**Patient 3**
Cirrhosis	Yes	Yes	Yes
Ribavirin	No	Yes	No
Treatment experienced	No	Yes	Yes
Age	41	56	49
Sex	M	M	F
MELD	19	13	11
Child-Pugh	9	8	5
Platelet	100	42	35
Albumin	28	24,5	36,3
W0 HCV RNA		2282346	9160000
W4 HCV RNA	31	ND	383
W12 HCV RNA	ND	ND	ND

Characteristics of the patients who have relapsed



HCV RNA at week 4 of treatment, at the end of treatment (EOT) and at week 12 after the end of treatment in patients treated without and with ribavirin: SVR12: 93,1% and 94,4% respectively



HCV RNA at week 4 of treatment, at the end of treatment (EOT) and at week 12 after the end of treatment according to the degree of fibrosis: SVR12: 100% and 88,9% for F3 and cirrhosis respectively.

3.Safety

No serious adverse event related to the treatment was observed.
Among patients treated with and without RBV,
4,17% and 4,56% had hemoglobin <10g/dL at W4
and 0% and 2,26% at W12, respectively.

Conclusions

Sofosbuvir in combination with Simeprevir +/- ribavirin in G4 HCV patients with advanced fibrosis achieved high SVR12 rates and was well tolerated.
Relapses were only observed in cirrhotic patients with advanced disease.

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HR: advisory board Janssen, Abbvie, MSD, BMS; SF: speaker/consultant for Gilead,
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