

Treatment Naïve and Treatment Experienced

Sofosbuvir + Ribavirin in HCV GT 4 Egyptian Ancestry Trial

Ruane PJ, et al. J Hepatol. 2015;62:1040-6.

Sofosbuvir and Ribavirin in HCV Genotype 4 Egyptian Ancestry Trial: Study Features

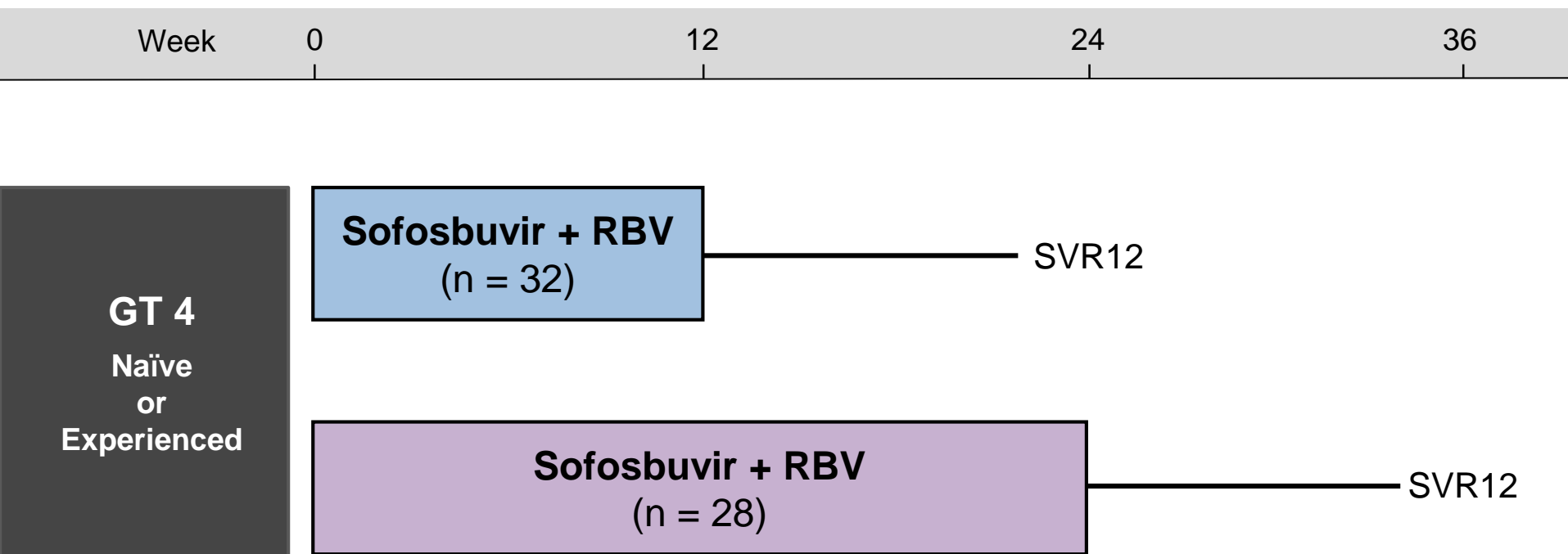
Egyptian Ancestry Genotype 4 Trial: Features

- **Design:** Randomized, open-label, phase 2 study of sofosbuvir + ribavirin in treatment-naïve and treatment-experienced patients with HCV GT 4
- **Setting:** single study center in United States
- **Entry Criteria**
 - HCV Genotype 4
 - Born in Egypt to two parents of Egyptian ancestry
 - Age 18 or older
 - Treatment naïve or treatment experienced
 - HCV RNA $\geq 10,000$ log IU/ml
 - Not co-infected with HIV
 - Patients with compensated cirrhosis allowed
 - Cirrhosis defined as: Fibrotest score > 0.75 plus APRI > 2 during screening
- **Primary End-Points:** Efficacy (SVR12) and safety

Sofosbuvir and Ribavirin in HCV Genotype 4 Egyptian Ancestry Trial: Baseline Characteristics

Chronic HCV GT4: Treatment with Sofosbuvir + Ribavirin		
Baseline Characteristic	SOF + RBV x 12 Weeks (n=31)	SOF + RBV x 24 Weeks (n=29)
Mean Age, y (range)	53 (26-62)	55 (27-75)
Male, n %	22 (71)	19 (66)
Mean BMI kg/m ² (range)	28.6 (21.3-34.5)	30.2 (19.9-42.3)
HCV Genotype		
4a	28 (90)	20 (69)
4II	1 (3)	1 (3)
4m	0	1 (3)
4n	1 (3)	2 (7)
4o	1 (3)	5 (17)
Cirrhosis, n %	7 (23)	7 (24)
<i>IL28B</i> CC genotype, n (%)	4 (13)	6 (21)
Treatment naïve, n (%)	14 (45)	14 (48)
HCV RNA, mean baseline log ₁₀ IU/ml	6.0	6.0

Sofosbuvir and Ribavirin in HCV Genotype 4 Egyptian Ancestry Trial: Design



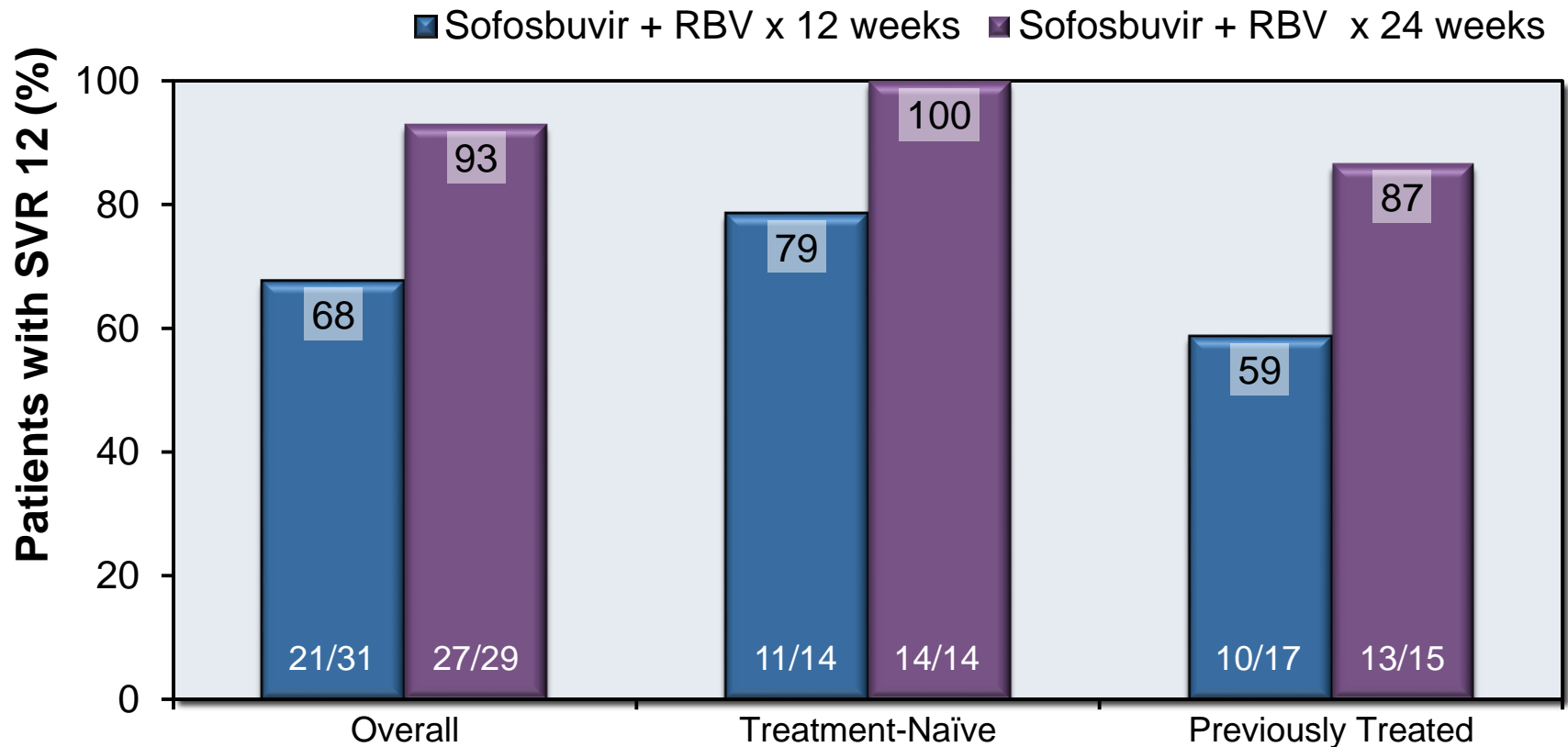
Drug Dosing

Sofosbuvir: 400 mg once daily

Weight-Based Ribavirin (in 2 divided doses): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

Sofosbuvir and Ribavirin in HCV Genotype 4 Egyptian Ancestry Trial: Results

SVR12 by Regimen Duration and Treatment Experience



Sofosbuvir and Ribavirin in HCV Genotype 4 Egyptian Ancestry Trial: Conclusions

Conclusions: “The findings from the present study suggest that 24weeks of sofosbuvir plus ribavirin is an efficacious and well tolerated treatment in patients with HCV genotype 4 infection.”

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Hepatitis C Online

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Hepatitis Web Study

<http://depts.washington.edu/hepstudy/>

Funded by a grant from the Centers for Disease Control and Prevention.