

Sofosbuvir + Ribavirin in HCV Recurrence Following Liver Transplantation

Charlton M, et al. Gastroenterology. 2015;148:108-17.

Sofosbuvir + Ribavirin in Recurrent HCV Post Liver Transplant

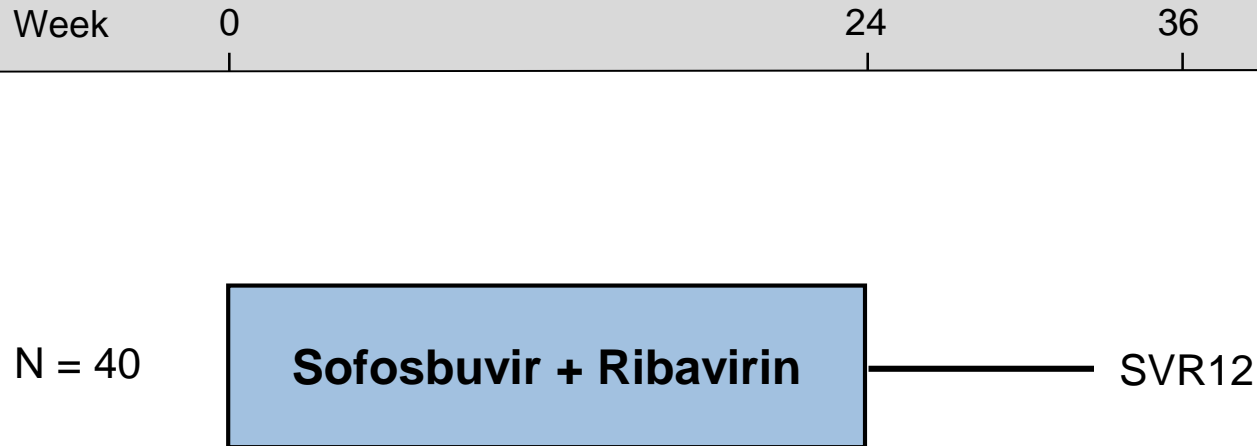
Sofosbuvir + Ribavirin Post Liver Transplant: Features

- **Design:** Open-label, prospective, single-arm, phase 2 trial of 24-week course of sofosbuvir + ribavirin in patients with HCV recurrence post-liver transplantation
- **Setting:** Multicenter, International Study
- **Entry Criteria**
 - N = 40 patients with chronic hepatitis C
 - Recurrent HCV infection post liver transplantation
 - Any genotype included
 - CTP score ≤ 7 and MELD score ≤ 17
 - Excluded if decompensated liver disease
- **Regimen (24 weeks)**
 - Sofosbuvir: 400 mg once daily
 - Ribavirin: started at 400 mg/day and increased up to 1200 mg/day
- **Primary End-Point:** SVR12

Sofosbuvir + Ribavirin in Recurrent HCV Post Liver Transplant

Baseline Characteristic (n = 40)	Sofosbuvir + Ribavirin x 12 weeks
Median Age, years (range)	59 (49 to 75)
Male sex, %	78
White, %	85
Median Body Mass Index (BMI) <30 kg/m ² (%)	75
HCV genotype 1 (%)	83
IL28B genotype CC, (%)	33
Median baseline HCV RNA, log ₁₀ IU/ml (range)	6.74 (4.49-7.59)
METAVIR-equivalent fibrosis (F3 or F4), %	F1-F2= 35%; F3=23%; F4=40%
Previous HCV treatment, %	88
Median time since liver transplantation, years (range)	4.3 (1.0-10.6)

Sofosbuvir + Ribavirin in Recurrent HCV Post Liver Transplant Design

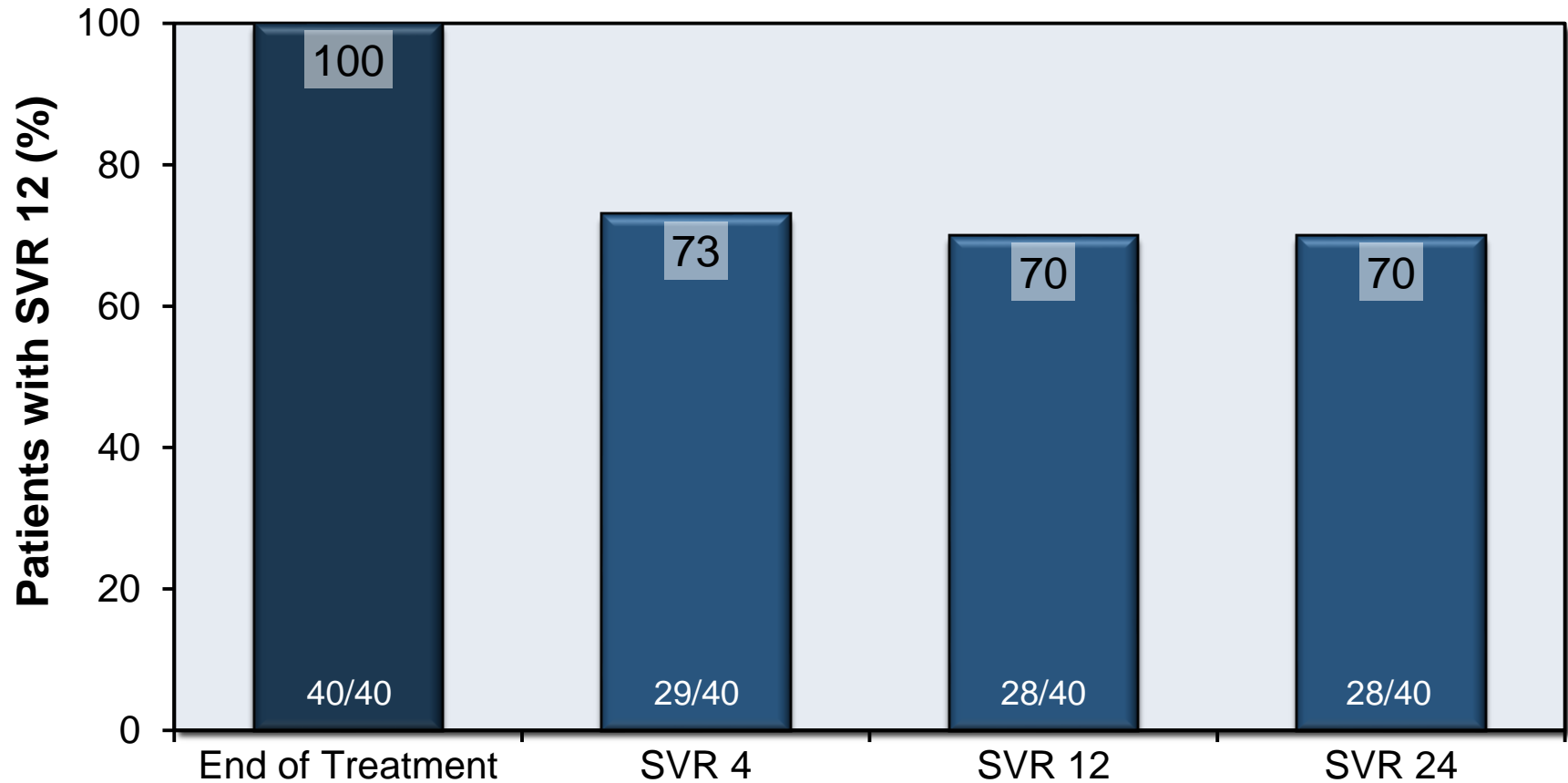


Drug Dosing

Sofosbuvir: 400 mg once daily

Ribavirin: administered in two divided daily doses (started at 400 mg/day and increased up to 1200 mg/day based on hemoglobin, creatinine clearance, and weight)

Sofosbuvir + Ribavirin in Recurrent HCV Post Liver Transplant Results



Source: Charlton M, et al. *Gastroenterology*. 2015;148:108-17.

Sofosbuvir + Ribavirin in Recurrent HCV Post Liver Transplant Adverse Effects

Event	Sofosbuvir + Ribavirin (n=40)
Any adverse event (%)	39 (98%)
Any serious adverse event	6 (15%)
Adverse event leading to discontinuation	2 (5%)
Adverse event occurring in >10% of patients	
Fatigue	12 (30%)
Diarrhea	11 (28%)
Headache	10 (25%)
Arthralgia	9 (23%)
Nausea	8 (20%)
Anemia	8 (20%)
Cough	7 (18%)
Insomnia	5 (13%)
Anxiety	5 (13%)

Source: Charlton M, et al. *Gastroenterology*. 2015;148:108-17.

Sofosbuvir + Ribavirin in Recurrent HCV Post Liver Transplant Conclusions

Conclusions: “Sofosbuvir and ribavirin combination therapy for 24 weeks is an effective and well tolerated interferon-free treatment for post-transplant HCV infection.”

This slide deck is from the University of Washington's *Hepatitis C Online* and *Hepatitis Web Study* projects.

Hepatitis C Online

www.hepatitisc.uw.edu

Hepatitis Web Study

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

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