

Sofosbuvir + Ribavirin to Prevent Post-Transplant HCV Recurrence

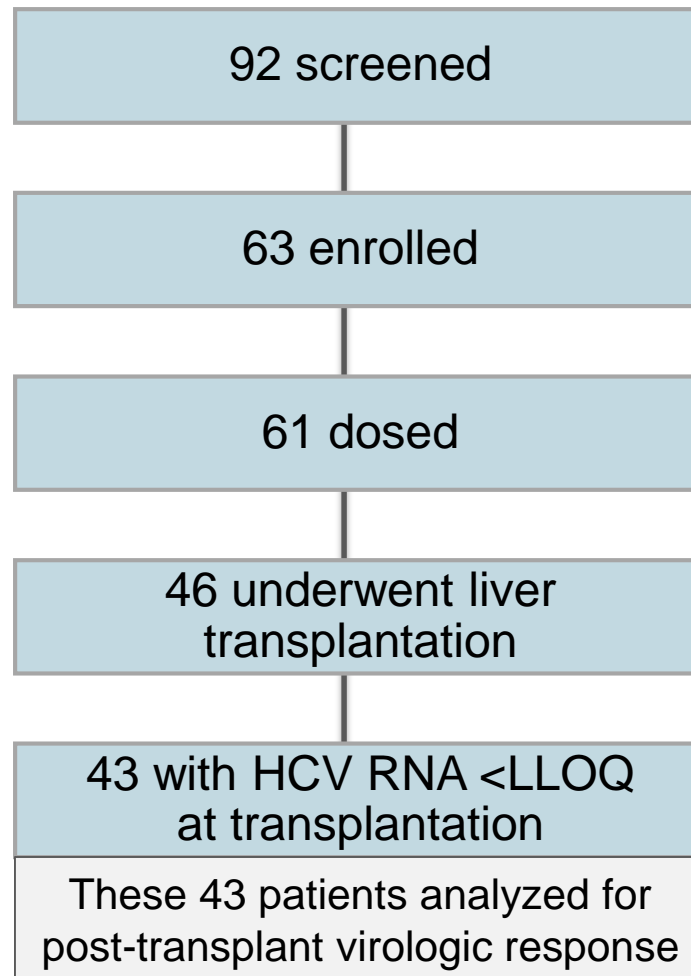
Curry MP, et al. Gastroenterology. 2014;September 24. [Epub ahead of print]

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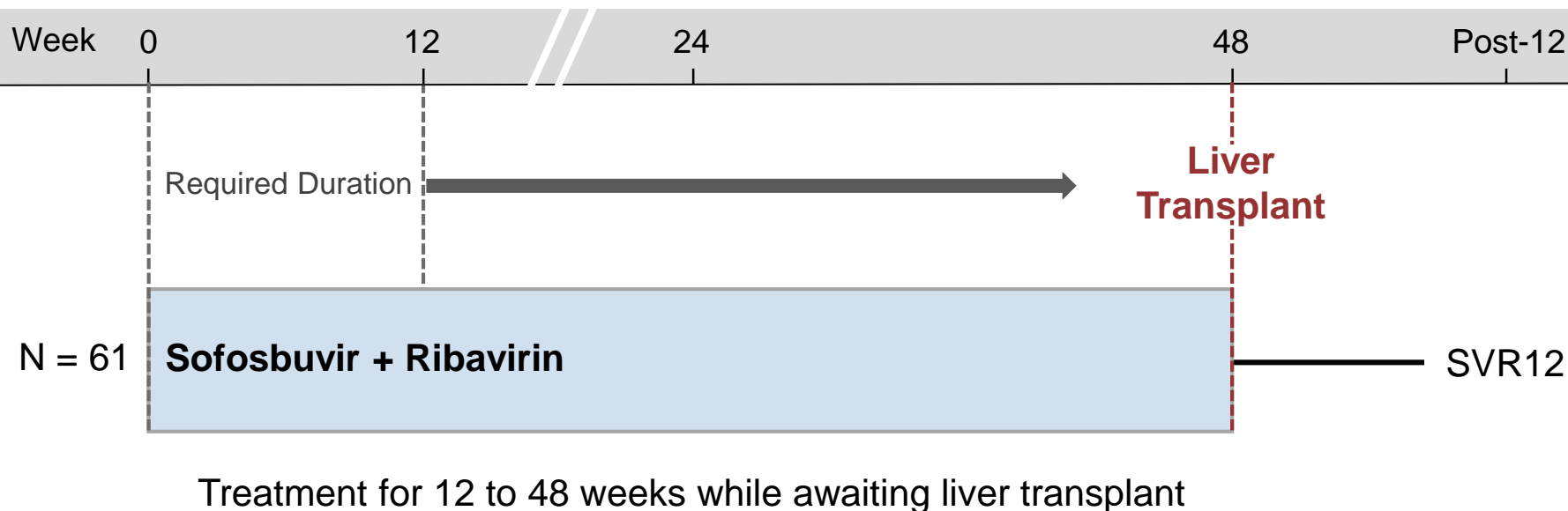
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- **Design:** Open-label, pilot, phase 2 trial of up to 48 weeks of sofosbuvir + ribavirin in patients with HCV of any genotype and cirrhosis awaiting liver transplantation for hepatocellular cancer
- **Setting:** International Study in United States, New Zealand, and Spain
- **Entry Criteria**
 - N = 61 patients with chronic hepatitis C and cirrhosis and any genotype
 - Age: ≥ 18
 - HCV RNA $\geq 10^4$ IU/mL
 - Treatment naïve and treatment experience
 - CTP score ≤ 7 and MELD score ≤ 17
 - Excluded if decompensated liver disease
- **Regimen Given Prior to Transplant (up to 48 weeks of therapy)**
 - Sofosbuvir + Ribavirin (weight based)
- **Primary End-Point:** SVR 12 weeks post transplant

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Drug Dosing

Sofosbuvir: 400 mg once daily

Ribavirin (weight-based and divided bid): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

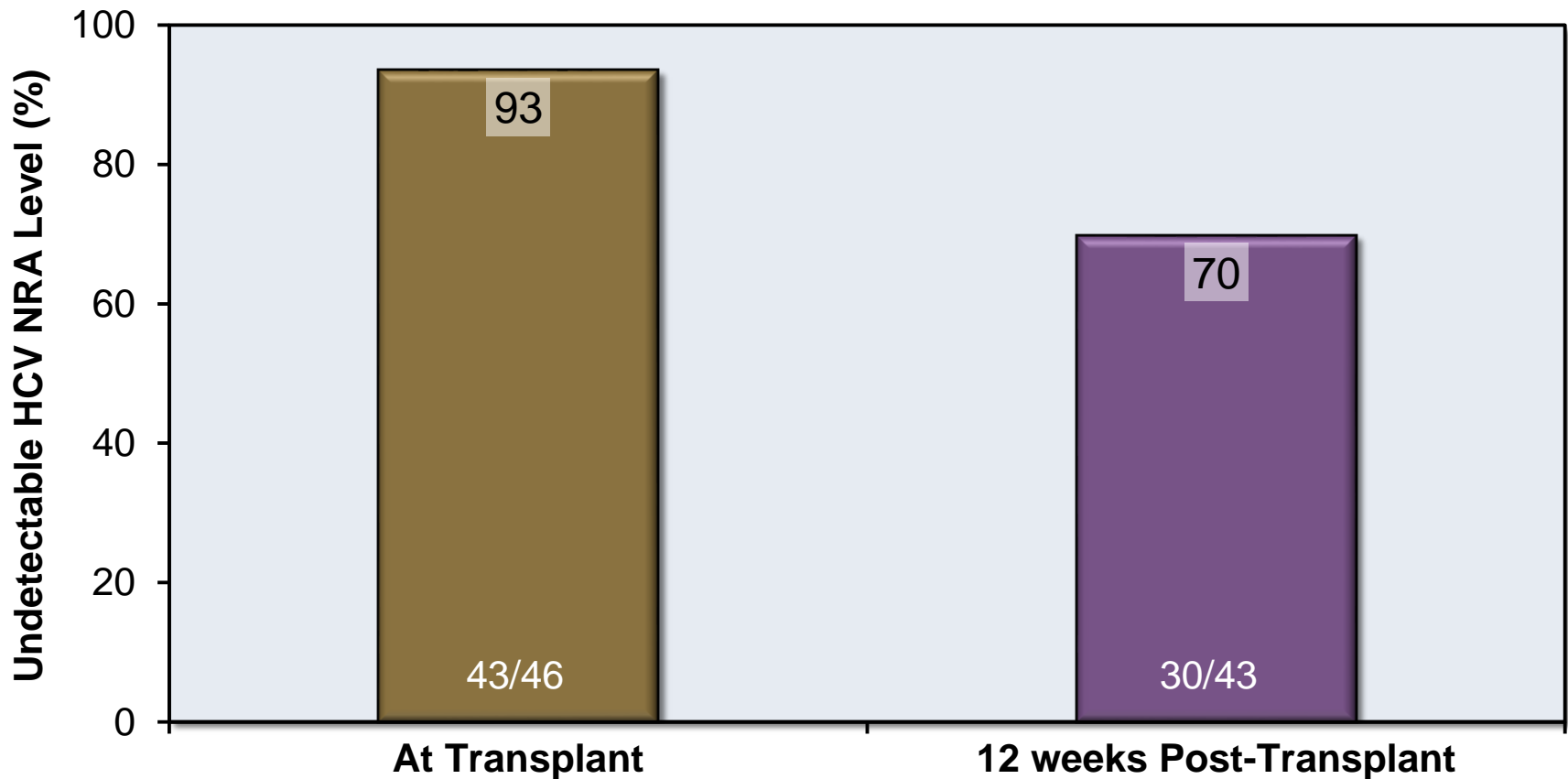
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Baseline Characteristic (n = 40)	All patients dosed (N=61)	All Patients transplanted with HCV RNA <25 IU/mL at time of transplant (N=43)
Median Age, years	59	59
Male sex, %	80	74
White, %	90	93
Median Body Mass Index (BMI) kg/m ²	27.4	27.1
HCV genotype 1 (%)	73	72
IL28B genotype CC, (%)	22	23
Median baseline HCV RNA, log ₁₀ IU/ml	6.2	6.3
Previous HCV treatment, %	75	79

Source: Curry MP, et al. *Gastroenterology*. 2014;September 24. [Epub ahead of print]

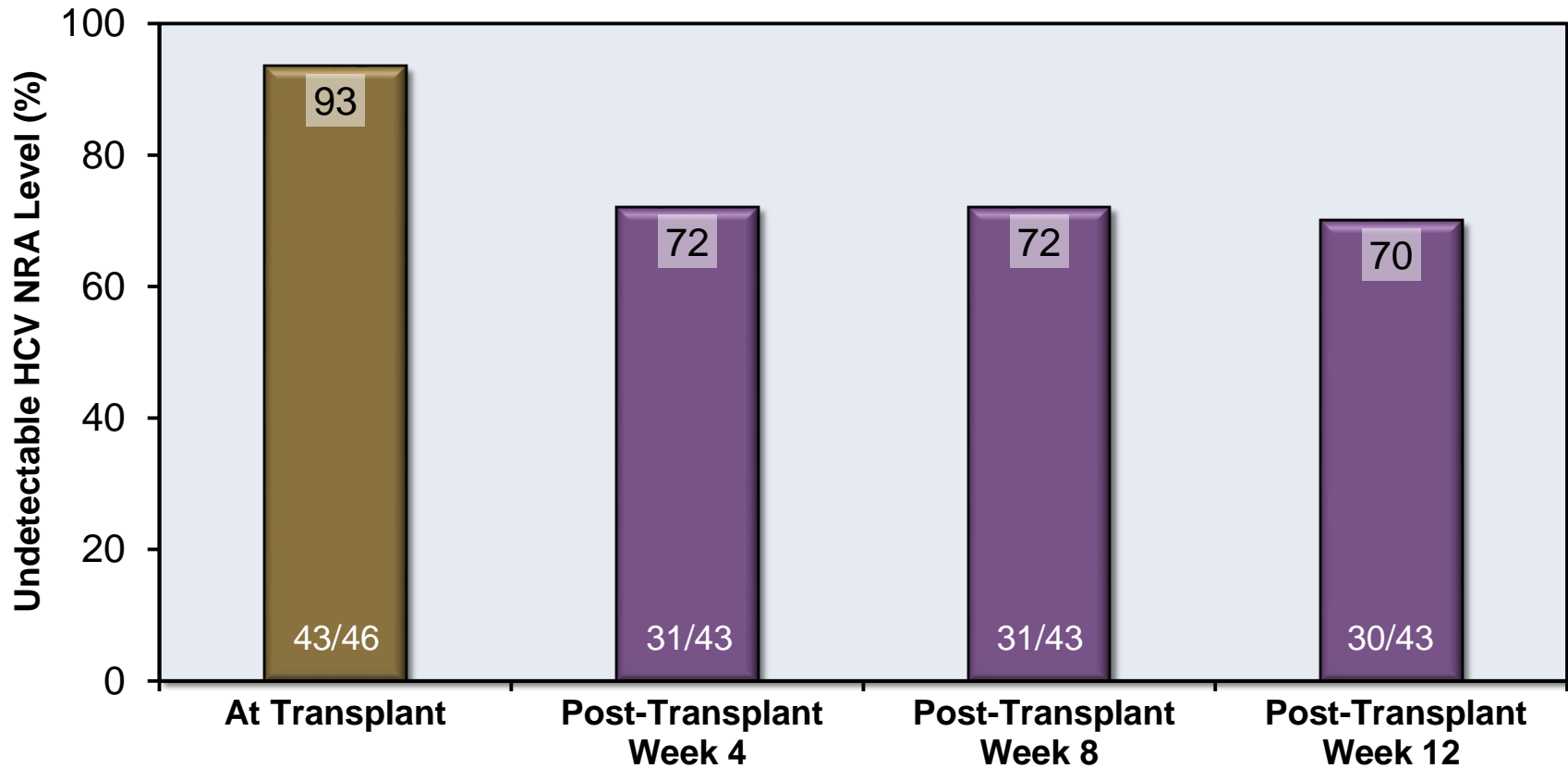
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Virologic Response at Transplant and Post-Transplant



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Virologic Response at Transplant and Post-Transplant



Data for the 43 patients with HCV RNA <25 IU/mL at time of transplant

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Event	Sofosbuvir + Ribavirin (N=61)
Any adverse event (%)	54 (8%)
Any serious adverse event	11 (18%)
Hemoglobin decrease to <10 g/dL	18 (30%)
Hemoglobin decrease to <8.5 g/dL	3 (5%)
Adverse event occurring in >10% of patients	
Fatigue	23 (38%)
Headache	14 (23%)
Nausea	10 (16%)
Rash	9 (15%)
Cough	7 (11%)
Dyspnea	7 (11%)
Insomnia	7 (11%)

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Conclusions

Conclusions: “Administration of sofosbuvir and ribavirin before liver transplantation can prevent post-transplant HCV recurrence.”

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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