Treatment-Naïve and Treatment-Experienced

Daclatasvir + Sofosbuvir + Ribavirin in HCV with Advanced Cirrhosis or Post-Liver Transplant

ALLY-1 Study

Poordad F, et al. Hepatology. 2016;63:1493-505.

DCV + SOF + RBV in Advanced Cirrhosis and Post-Liver Transplant
ALLY-1: Results

ALLY-1: Features

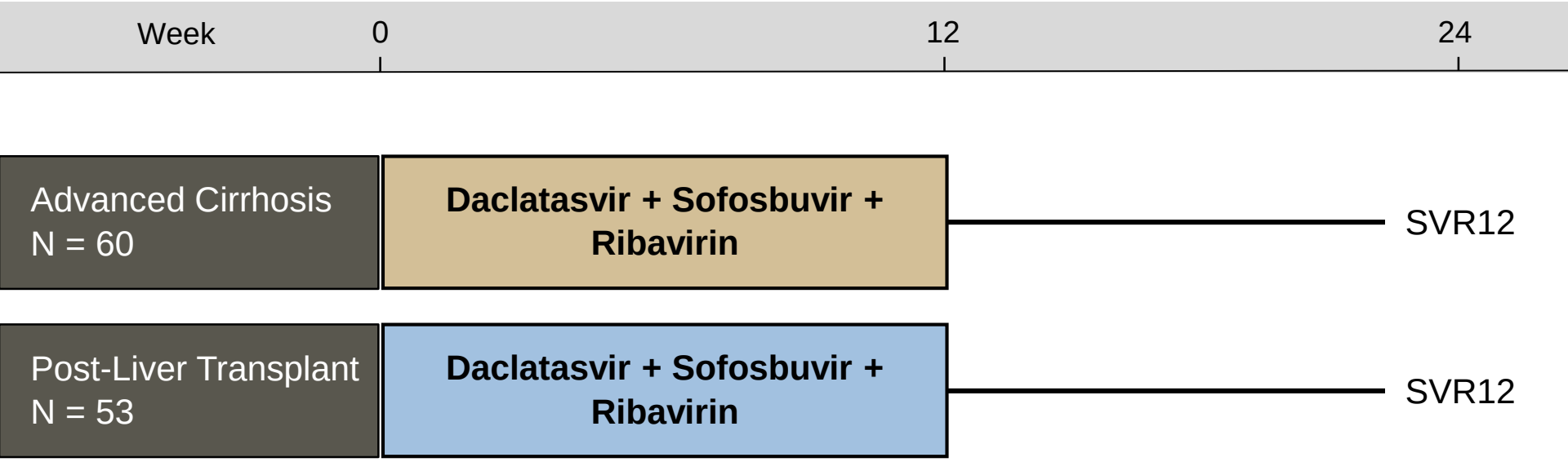
- **Design**: **Design**: Multicenter, prospective, open-label, phase 3 study of daclatasvir plus sofosbuvir plus ribavirin in treatment-naïve and treatment-experienced patients with advanced cirrhosis or post-liver transplant HCV recurrence.
- **Setting**: Five centers in United States
- **Entry Criteria**
  - Treatment-naïve or treatment-experienced
  - Chronic HCV genotypes 1-6
  - HCV RNA >10,000 IU/ml
  - Cirrhosis (compensated and decompensated) allowed
  - Post-liver transplant: received transplant ≥3 months prior to screening
- **Outcome Measure**: Primary = SVR12

Source: Poordad F, et al. Hepatology. 2016;63:1493-505.

DCV + SOF + RBV in Advanced Cirrhosis and Post-Liver Transplant

ALLY-1: Results

ALLY-1: Study Design



Drug Dosing
Daclatasvir: 60 mg once daily
Sofosbuvir: 400 mg once daily
Ribavirin: 600 mg daily, adjusted to 1000 mg/day based on hemoglobin levels and renal function

Source: Poordad F, et al. Hepatology. 2016;63:1493-505.

DCV + SOF + RBV in Advanced Cirrhosis and Post-Liver Transplant

ALLY-1: Patient Characteristics

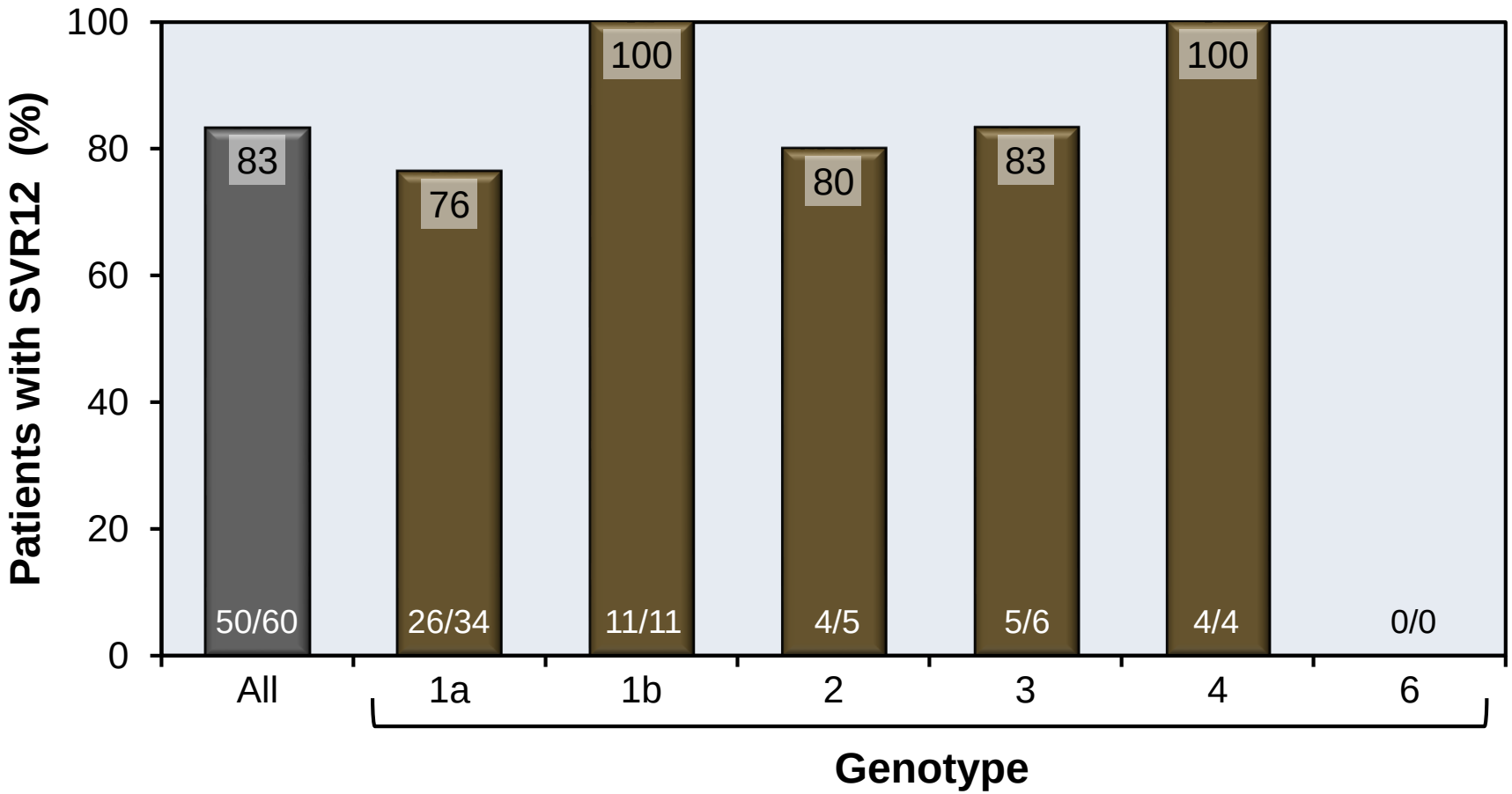
Characteristic	Advanced Cirrhosis (n=60)	Post-Liver Transplant (n=53)
Male, n (%)	38 (63%)	38 (72%)
Median age, years (range)	58 (19-75)	59 (22-82)
Race		
White	57 (95%)	51 (96%)
Black/African American	3 (5%)	1 (2%)
Asian	0 (0%)	1 (2%)
HCV genotype		
1a	34 (57%)	31 (58%)
1b	11 (18%)	10 (19%)
2	5 (8%)	0 (0%)
3	6 (10%)	11 (21%)
4	4 (7%)	0 (0%)
6	0	1 (2%)
Mean HCV RNA $\log_{10}$ (IU/mL)	6.01	6.61

Source: Poordad F, et al. Hepatology. 2016;63:1493-505.

DCV + SOF + RBV in Advanced Cirrhosis and Post-Liver Transplant

ALLY-1: Results for Advanced Cirrhosis Cohort

ALLY-1: SVR12 Results for Advanced Cirrhosis Cohort by Genotype



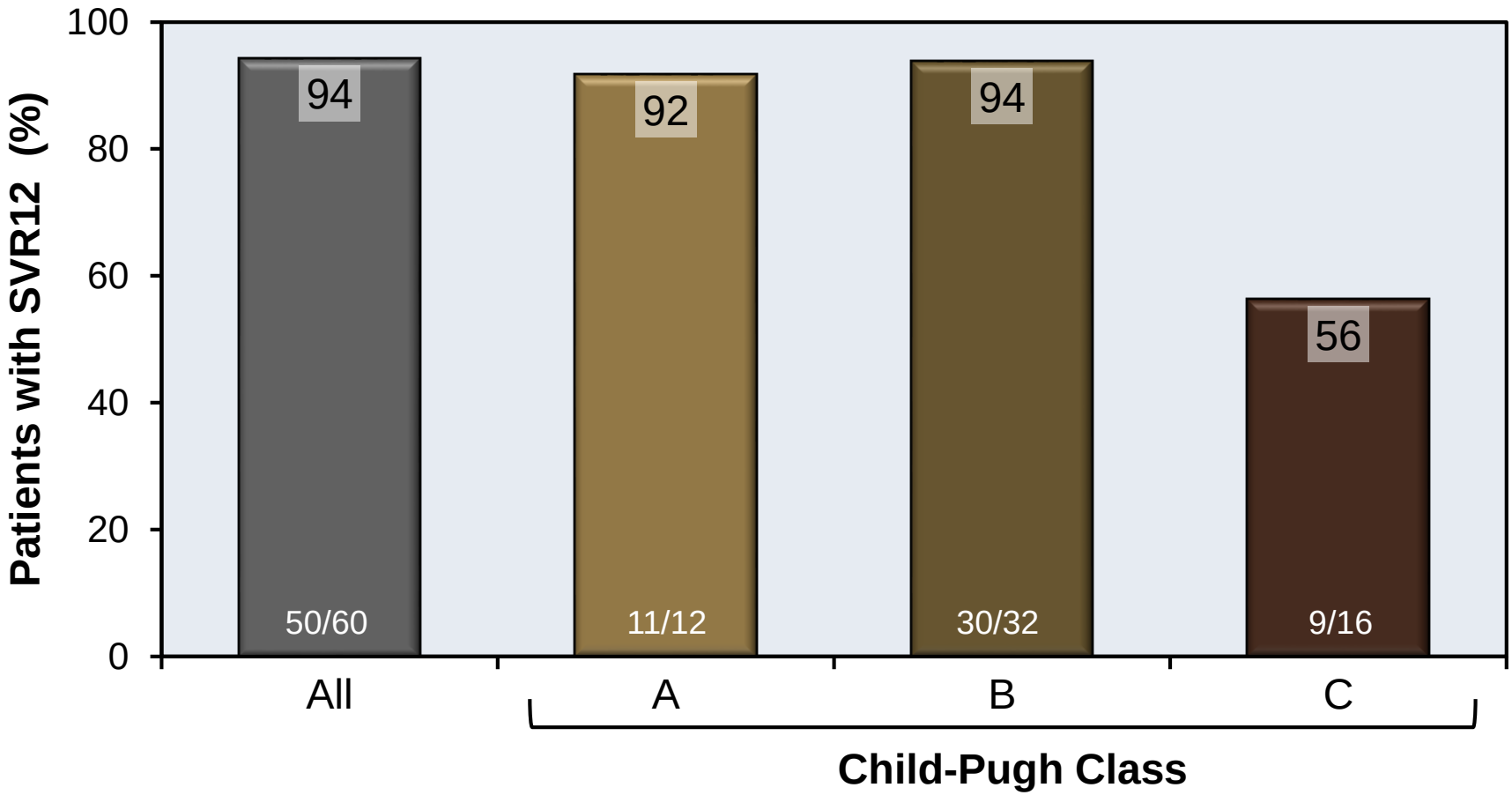
Source: Poordad F, et al. Hepatology. 2016;63:1493-505.

Hepatitis web study

DCV + SOF + RBV in Advanced Cirrhosis and Post-Liver Transplant

ALLY-1: Results for Advanced Cirrhosis Cohort

ALLY-1: SVR12 Results for Advanced Cirrhosis Cohort by Child-Pugh Class

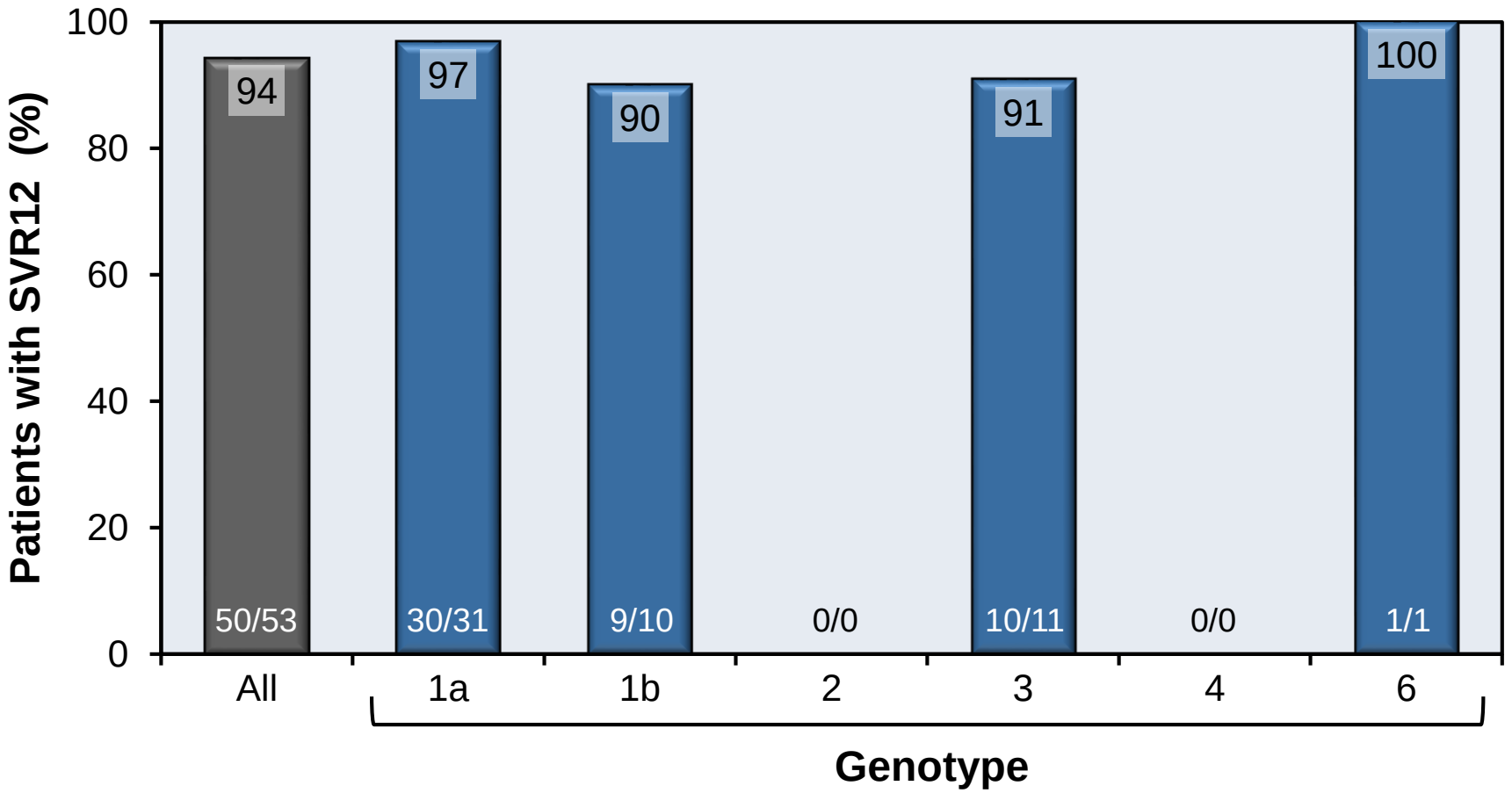


Source: Poordad F, et al. Hepatology. 2016;63:1493-505.

DCV + SOF + RBV in Advanced Cirrhosis and Post-Liver Transplant

ALLY-1: Results for Post-Liver Transplant Cohort

ALLY-1: SVR12 Results for Post-Liver Transplant Cohort by Genotype



Source: Poordad F, et al. Hepatology. 2016;63:1493-505.

Hepatitis web study

DCV + SOF + RBV in Advanced Cirrhosis and Post-Liver Transplant
ALLY-1: Conclusion

Conclusion: “The pan-genotypic combination of daclatasvir, sofosbuvir, and ribavirin was safe and well tolerated. High SVR rates across multiple HCV genotypes were achieved by patients with post-liver transplant recurrence or advanced cirrhosis.”

Source: Poordad F, et al. Hepatology. 2016;63:1493-505.

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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