Treatment Experienced

Sofosbuvir + Peginterferon + Ribavirin in Genotype 2 or 3

LONESTAR-2

Lawitz E, et al. Hepatology. 2015:61:769-75.

Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3
LONESTAR-2 Trial: Features

LONESTAR-2 Trial: Features

- **Design**: Open-label, single-arm, phase 2 trial of 12-week course of sofosbuvir + peginterferon + ribavirin in treatment-experienced patients with HCV GT 2 or 3
- **Setting**: Texas Liver Institute
- **Entry Criteria**
  - N = 47 patients with chronic hepatitis C
  - Previously failed treatment with peginterferon plus ribavirin
  - Excluded if coinfected with HIV or HBV
  - HCV genotype 2 (49%) or 3 (51%)
  - Compensated cirrhosis allowed
- **Regimen (All x 12 weeks)**
  - Sofosbuvir: 400 mg once daily
  - Peginterferon alfa-2a: 180 µg once weekly
  - Ribavirin (weight based): 1000-1200 mg/day in 2 divided doses
- **Primary End-Point**: SVR12

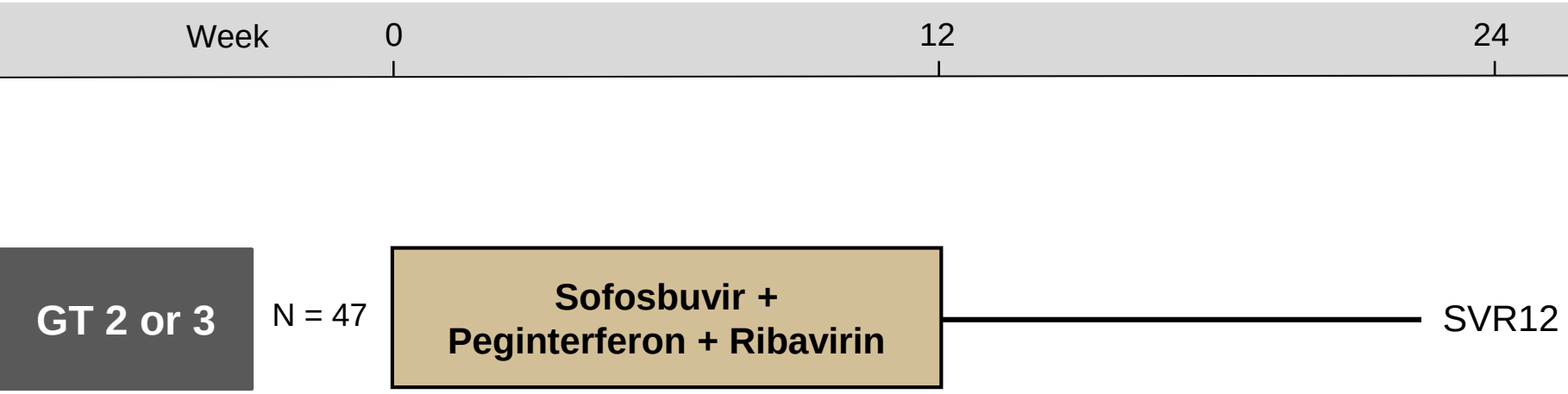
Source: Lawitz E, et al. Hepatology. 2015:61:769-75.

Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3
LONESTAR-2 Trial: Patient Demographics

Baseline Characteristic	SOF + PEG + RBV x 12 weeks (n = 47)
Age, mean (range)	56 (39-72)
Male, n (%)	32 (68)
White, n (%)	45 (96)
Hispanic, n (%)	21 (45)
Mean Body Mass Index (BMI) kg/m^2 (range)	31 (21-53)
IL28B CC, n (%)	17 (36)
HCV GT3	24 (51)
Mean baseline HCV RNA, log_{10} IU/ml (range)	6.2 (4.0-7.2)
Cirrhosis, %	26 (55)
Prior Relapse / virologic breakthrough	40 (85)

Source: Lawitz E, et al. Hepatology. 2015:61:769-75.

Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3
LONESTAR-2 Trial: Design

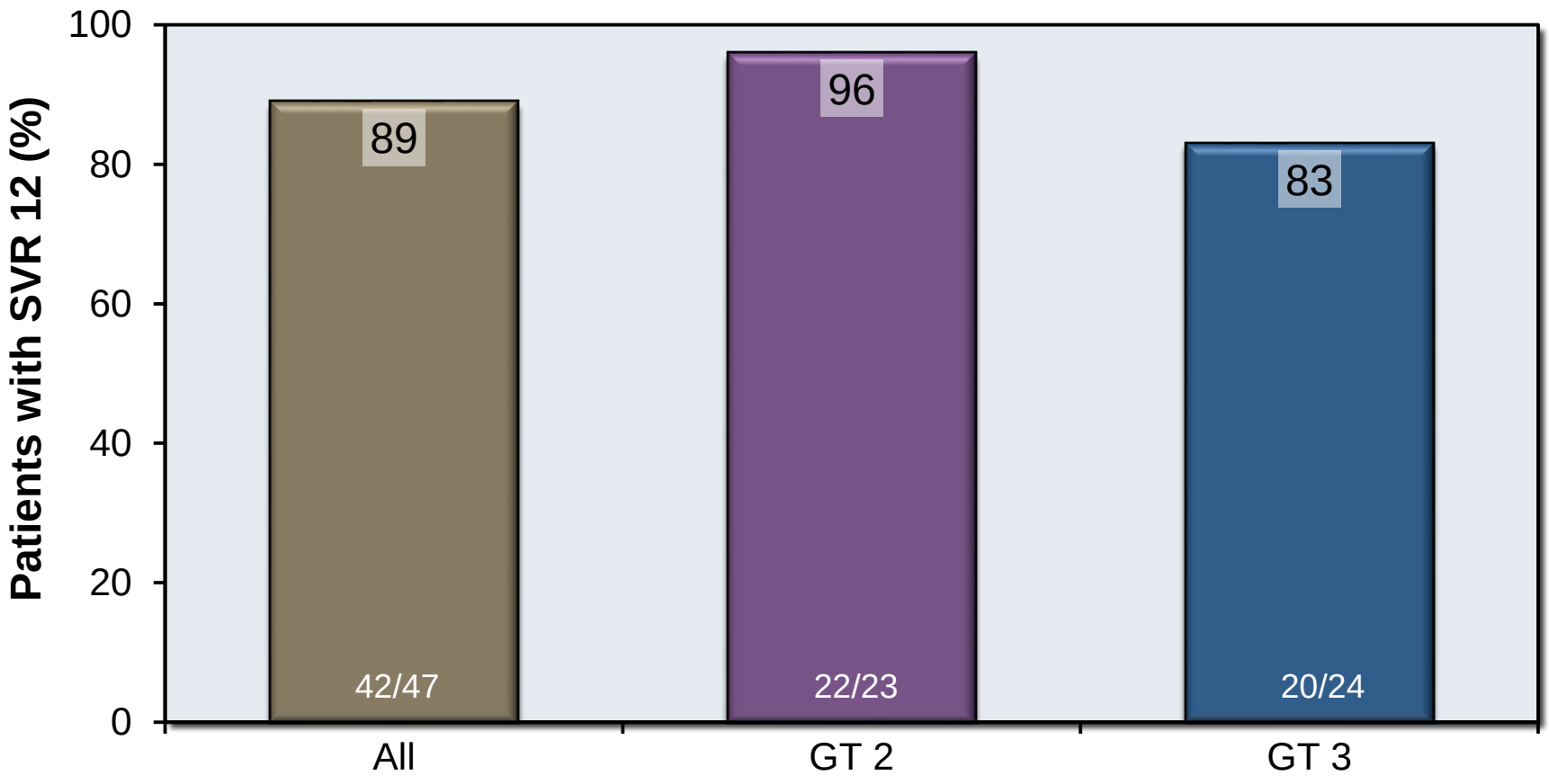


Drug Dosing
Sofosbuvir: 400 mg once daily
Peginterferon alfa-2a: 180 µg once weekly
Ribavirin (weight-based and in 2 divided doses): 1000 mg/day if < 75 kg or 1200 mg/day if ≥ 75 kg

Source: Lawitz E, et al. Hepatology. 2015:61:769-75.

Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3
LONESTAR-2 Trial: Results

SVR12 in Treatment-Experienced by HCV Genotype

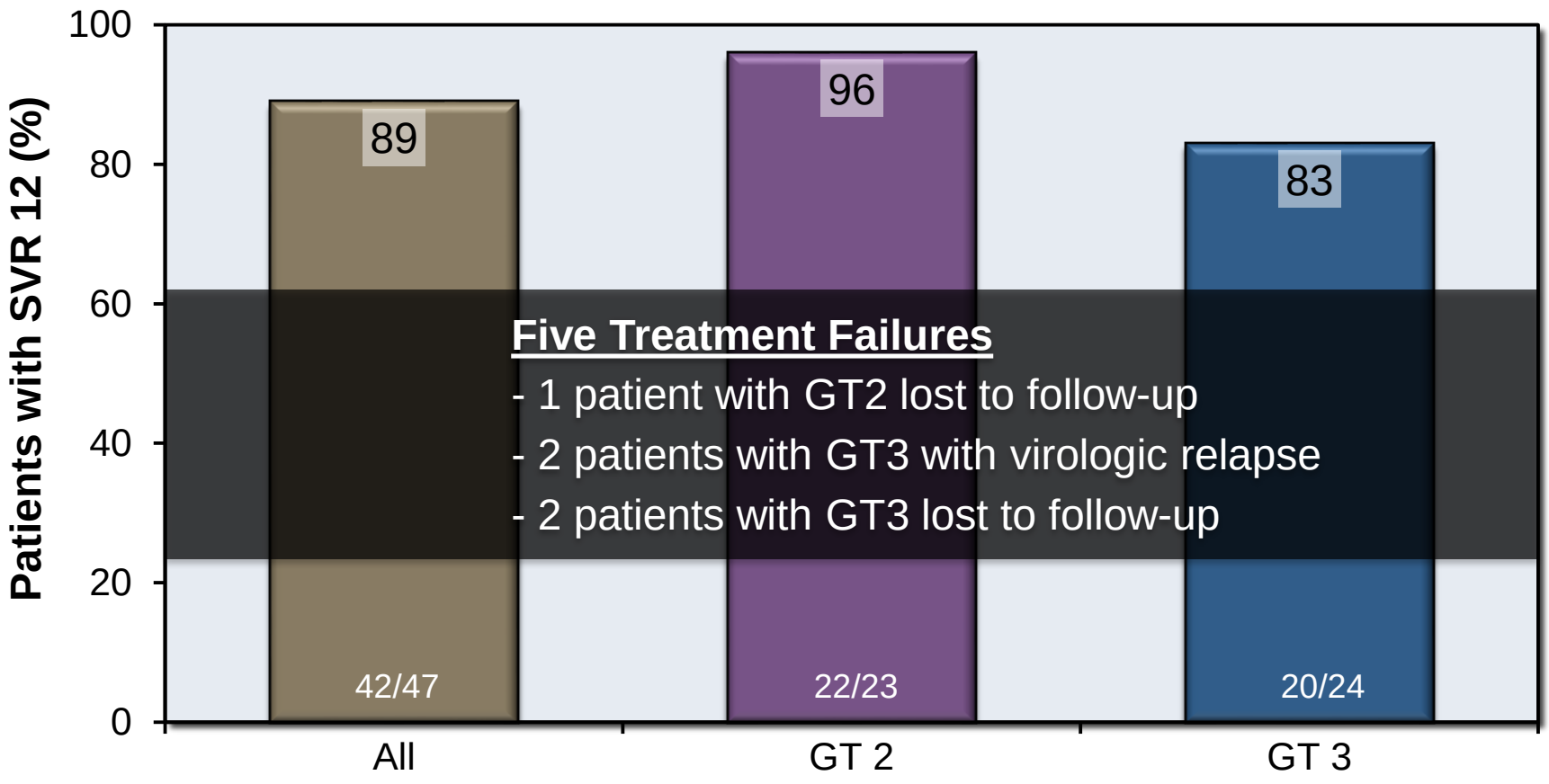


Source: Lawitz E, et al. Hepatology. 2015:61:769-75.

Hepatitis web study

Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3
LONESTAR-2 Trial: Results

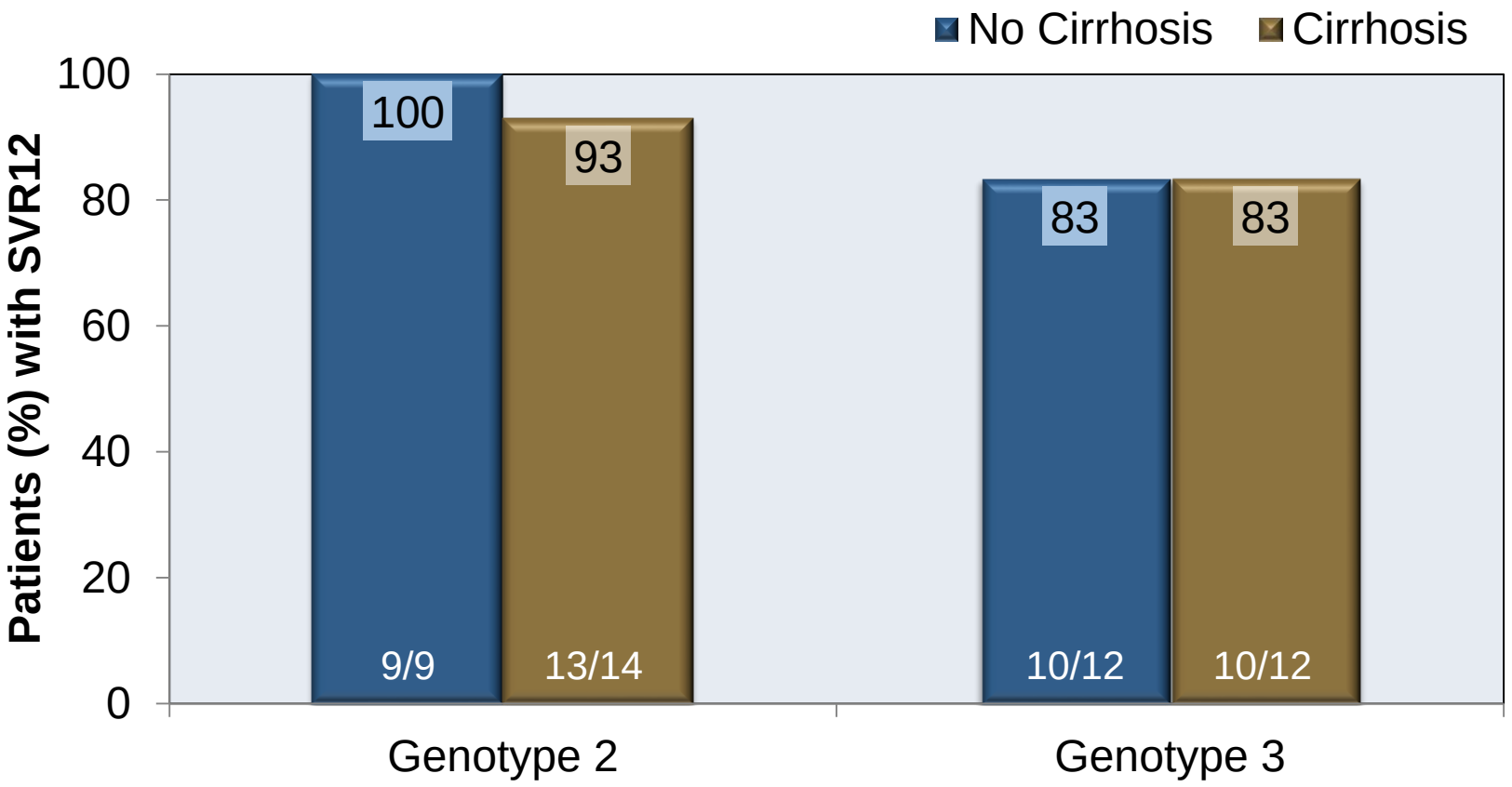
SVR12 in Treatment-Experienced by HCV Genotype



Source: Lawitz E, et al. Hepatology. 2015:61:769-75.

Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3
LONESTAR-2 Trial: Results

LONESTAR-2 Trial: SVR12 by Cirrhosis Status



Source: Lawitz E, et al. Hepatology. 2015:61:769-75.

Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3
LONESTAR-2 Trial: Adverse Events

LONESTAR-2: Adverse Events in ≥ 15% of Patients	
Preferred Term, n (%)	SOF + PEG + RBV x 12 weeks (n = 47)
Any Adverse Event	45 (96)
Flu-like Symptoms	26 (55)
Fatigue	15 (32)
Anemia	14 (30)
Neutropenia	11 (23)
Nausea	8 (17)
Headache	7 (15)
Rash	7 (15)
Thrombocytopenia	7 (15)

Source: Lawitz E, et al. Hepatology. 2015:61:769-75.

Sofosbuvir + PEG + RBV in Treatment-Experienced HCV GT 2 or 3
LONESTAR-2 Trial: Conclusion

Conclusions: “In treatment-experienced patients with HCV genotypes 2 and 3, 12-week administration of sofosbuvir + peginterferon + ribavirin provided high SVR rates, irrespective of cirrhosis status. No safety concerns were identified.”

Source: Lawitz E, et al. Hepatology. 2015:61:769-75.

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/

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

Hepatitis web study