Treatment-Naïve and Treatment-Experienced

Daclatasvir + Sofosbuvir in Genotype 3

ALLY-3 Study

Nelson DR, et al. Hepatology 2015;61:1127-35.

Hepatitis
web study

Daclatasvir + Sofosbuvir for HCV GT 3
ALLY-3 Trial: Study Features

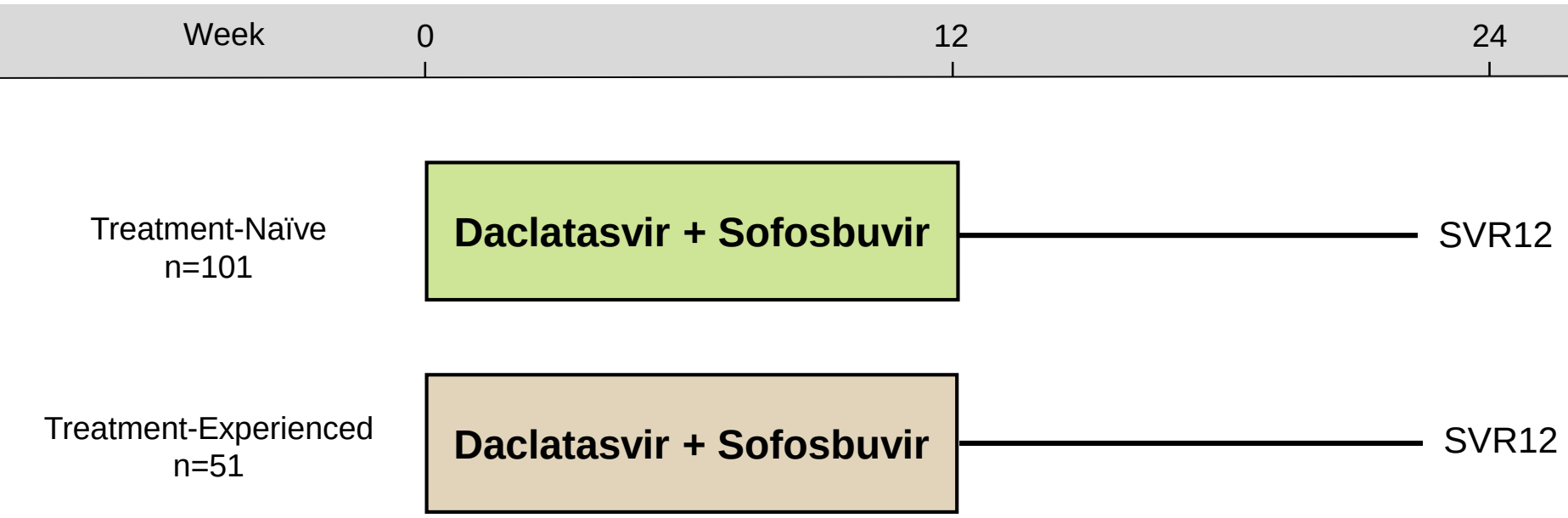
Daclatasvir + Sofosbuvir Trial: Features

- **Design**: Phase 3 open-label two-cohort study of daclatasvir (DCV) plus sofosbuvir (SOF) in treatment-naïve or experienced, chronic HCV GT 3
- **Setting**: Multiple centers in the United States
- **Entry Criteria**
  - Chronic HCV genotype 3
  - Treatment-naïve or treatment-experienced (prior NS5A experience excluded)
  - HCV RNA ≥10,000 IU/ml
  - Compensated cirrhosis allowed (METAVIR F4 on biopsy, FibroScan >14.6 kPa or FibroTest (*FibroSURE*) score ≥0.75 with APRI >2)
- **Patient Groups**
  - N = 101 treatment-naïve GT3: DCV + SOF x 12 weeks
  - N = 51 treatment-experienced GT3: DCV + SOF x 12 weeks
- **End-Points**: Primary = SVR12

Source: Nelson DR, et al. Hepatology 2015;61:1127-35.

Hepatitis web study

Daclatasvir + Sofosbuvir for HCV GT 3
ALLY-3 Trial: Design



Drug Dosing
Daclatasvir: 60 mg once daily
Sofosbuvir: 400 mg once daily

Source: Nelson DR, et al. Hepatology 2015;61:1127-35.

Hepatitis web study

Daclatasvir + Sofosbuvir for HCV GT 3
ALLY-3 Trial: Patient Characteristics

Characteristic	Treatment-Naïve (n=101)	Treatment-Experienced (n=51)
Male	58 (57%)	32 (63%)
Median age, years (range)	53 (24-67)	58 (40-73)
Race		
White	92 (91%)	45 (88%)
Black	4 (4%)	2 (4%)
Asian	5 (5%)	2 (4%)
HCV RNA ≥800,000 IU/ml	70 (69%)	38 (75%)
Cirrhosis	19 (19%)	13 (25%)
IL28B non-CC genotype	61 (60%)	31 (61%)
Prior treatment failure		
Relapse	N/A	31 (61%)
Partial response	N/A	2 (4%)
Null response	N/A	7 (14%)
Other[a]	N/A	11 (22%)

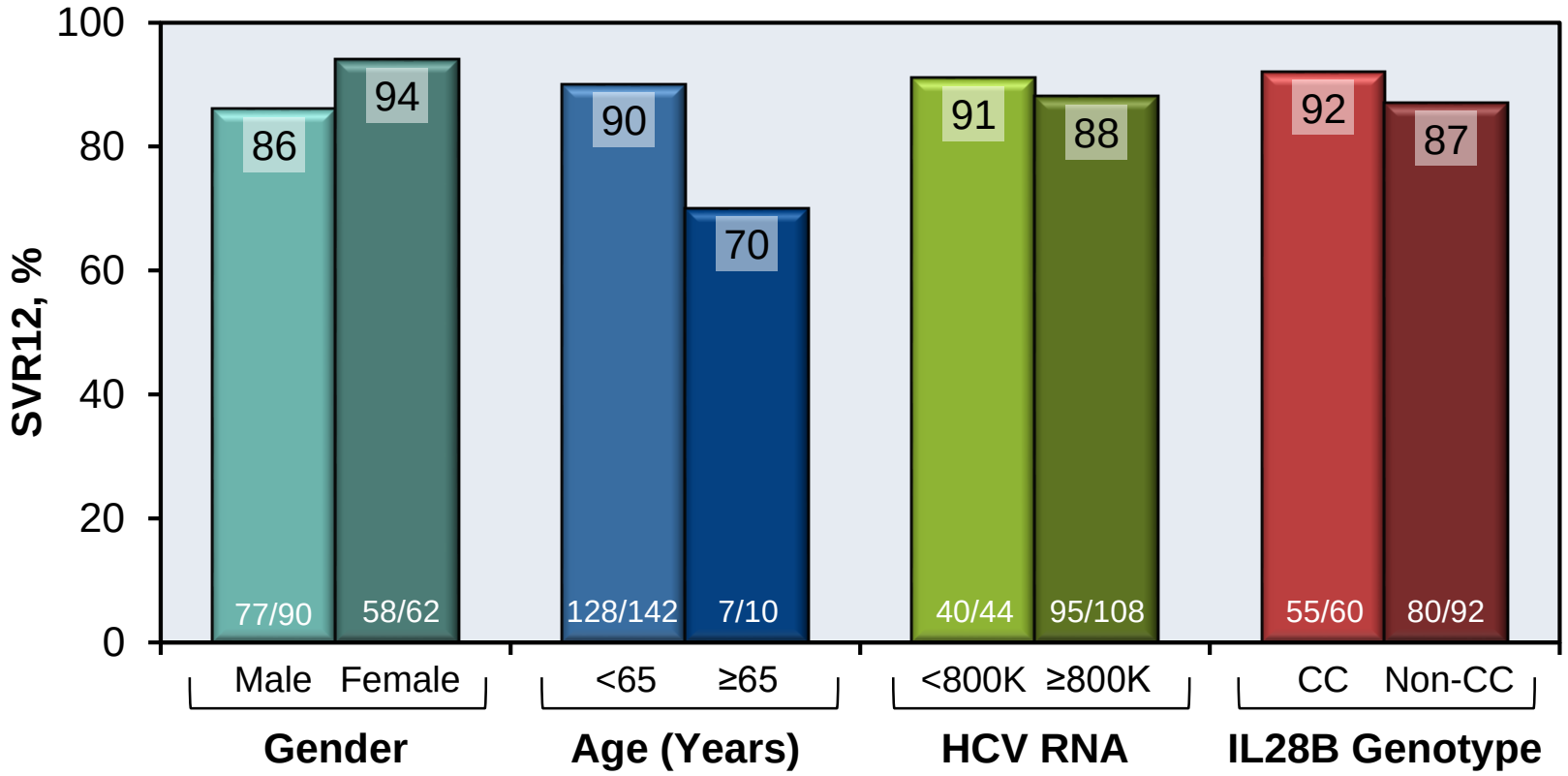
[a] Intolerant of therapy (n=6), virologic breakthrough (n=2), HCV never undetectable on treatment (n=2)

Source: Nelson DR, et al. Hepatology 2015;61:1127-35.

Hepatitis web study

Daclatasvir + Sofosbuvir for HCV GT 3
ALLY-3 Trial: Results

ALLY-3: SVR12, by Baseline Characteristics Status



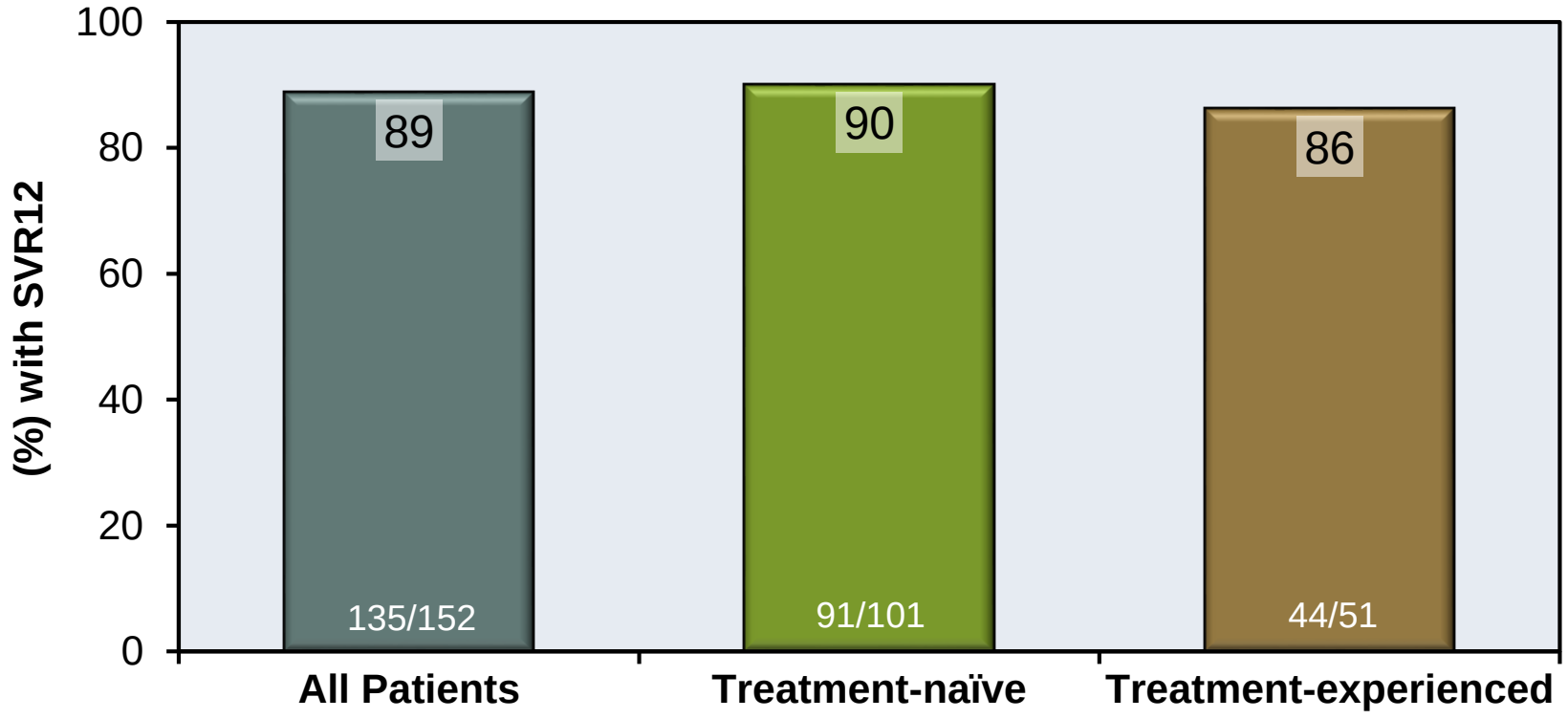
Note: SVR 12 based on HCV RNA less than lower limit of quantitation (25 IU/mL), detectable or undetectable

Source: Nelson DR, et al. Hepatology 2015;61:1127-35.

Hepatitis web study

Daclatasvir + Sofosbuvir for HCV GT 3
ALLY-3 Trial: Results

ALLY-3: SVR12, by Cirrhosis Status

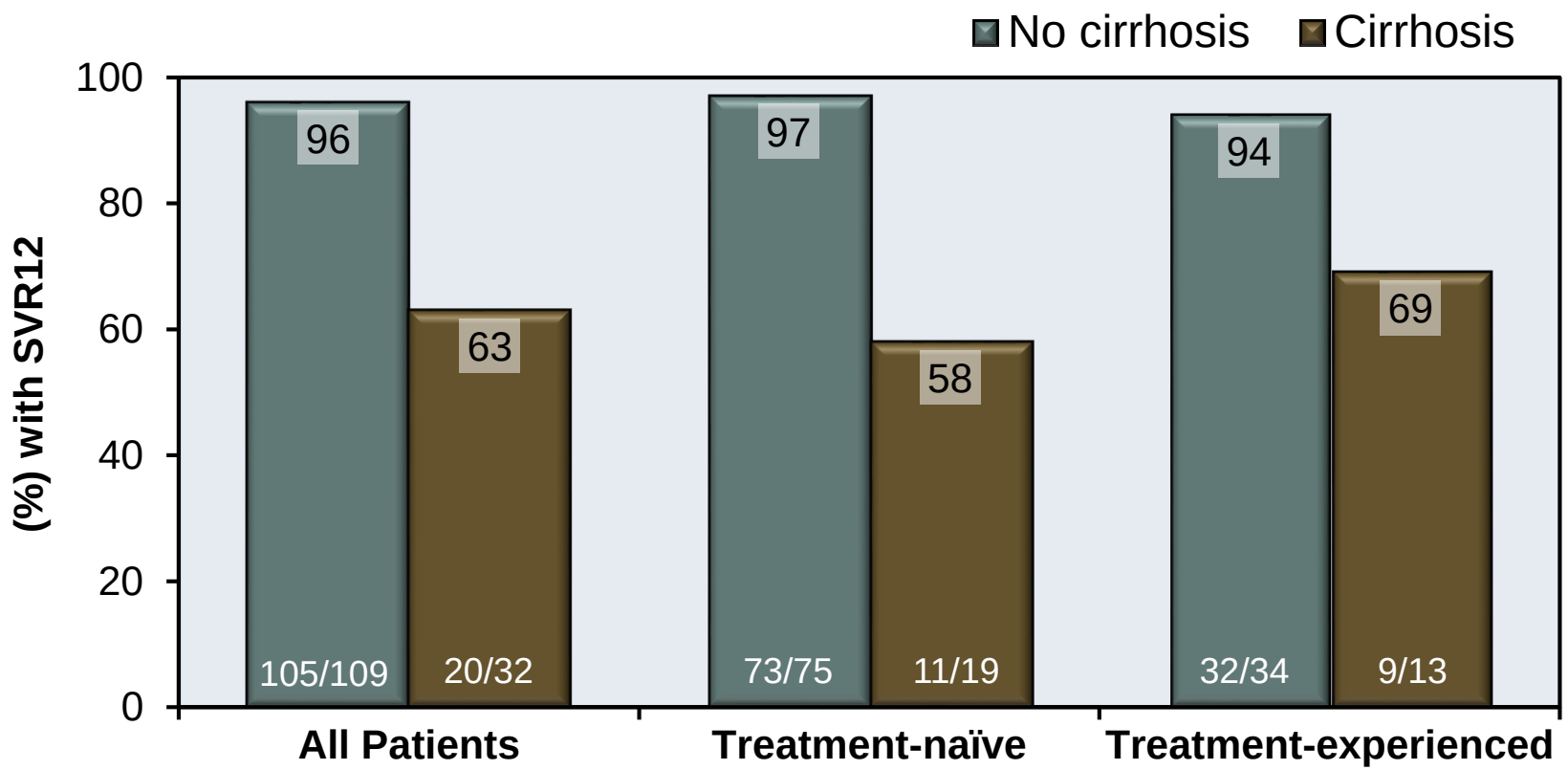


Source: Nelson DR, et al. Hepatology 2015;61:1127-35.

Hepatitis web study

Daclatasvir + Sofosbuvir for HCV GT 3
ALLY-3 Trial: Results

ALLY-3: SVR12, by Cirrhosis Status



Note:11 had missing or inconclusive findings for cirrhosis and not included in denominators

Source: Nelson DR, et al. Hepatology 2015;61:1127-35.

Hepatitis web study

Daclatasvir + Sofosbuvir for HCV GT 3
ALLY-3 Trial: Adverse Events

Event	Daclatasvir + Sofosbuvir (n=152)
Serious Adverse Events (AEs)	1 (1%)
AEs leading to discontinuation	0
Grade 3 or 4 AEs	3[a] (2%)
Adverse Events in ≥10% of patients	
Headache	30 (20%)
Fatigue	29 (19%)
Nausea	18 (12%)
Grade 3 or 4 Lab Abnormalities	
Hemoglobin < 9 g/dL	0
Neutrophils < 0.75 x 10^9/L	0
Platelets < 50 x 10^9/L	2 (1%)
Lipase > 3 x ULN	3 (2%)

[a]All were grade 3 AEs. ULN = upper limit of normal

Source: Nelson DR, et al. Hepatology 2015;61:1127-35.

Hepatitis web study

Daclatasvir + Sofosbuvir for HCV GT 3
ALLY-3 Trial: Conclusion

Conclusion: “A 12-week regimen of daclatasvir plus sofosbuvir achieved SVR12 in 96% of patients with genotype 3 infection without cirrhosis and was well tolerated. Additional evaluation to optimize efficacy in genotype 3-infected patients with cirrhosis is underway.”

Source: Nelson DR, et al. Hepatology 2015;61:1127-35.

Hepatitis web study

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