

Treatment-Naïve and Treatment-Experienced

Daclatasvir + Sofosbuvir +/- Ribavirin in Genotype 1-3 A1444040 Trial

Sulkowski MS, et al. N Engl J Med. 2014;370:211-21.

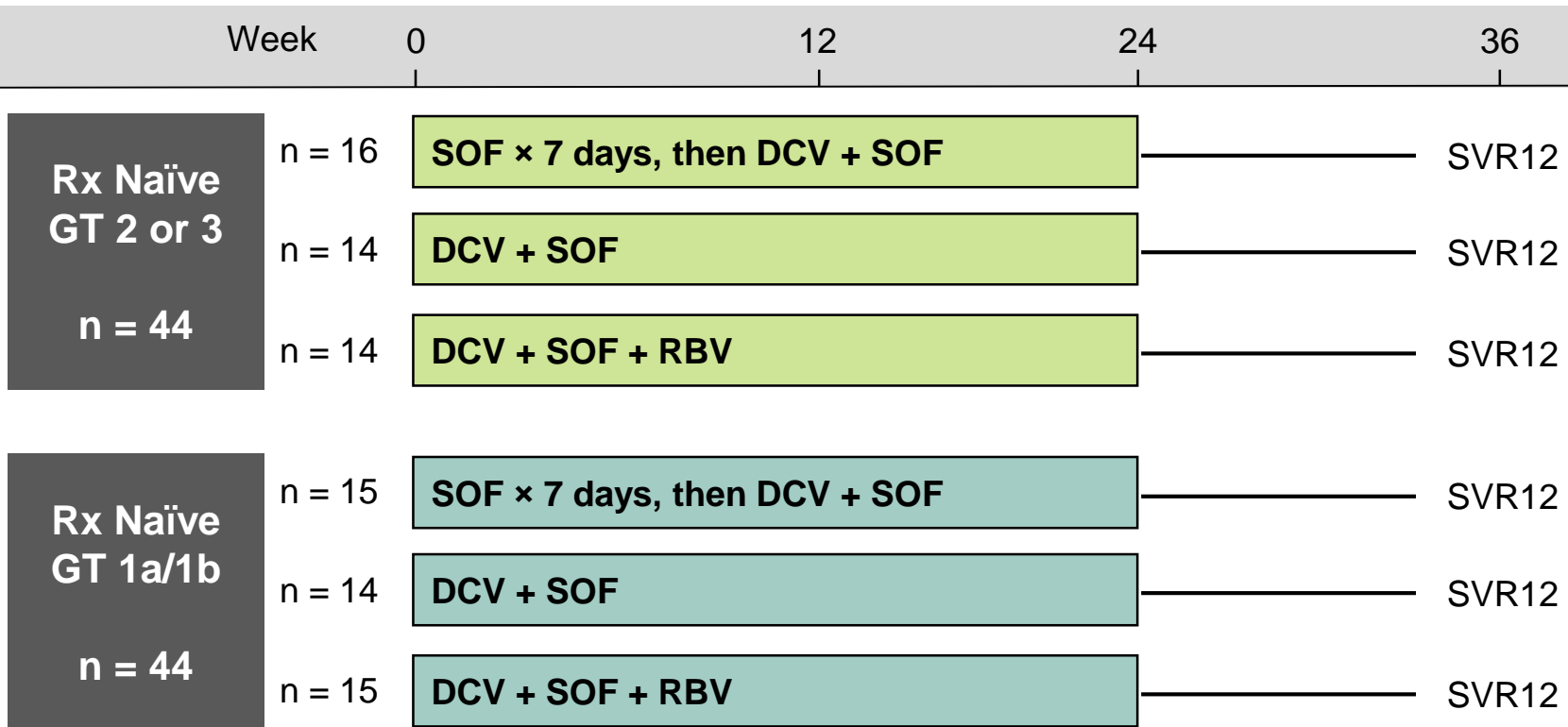
Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3 A1444040 Trial: Study Features

Daclatasvir + Sofosbuvir Trial: Features

- **Design:** Randomized, open-label, phase 2a trial, using daclatasvir plus sofosbuvir with or without ribavirin in treatment naive or experienced, chronic HCV GT 1-3
- **Setting:** United States
- **Entry Criteria**
 - Chronic HCV Genotype 1, 2, or 3
 - Treatment-naïve or treatment-experienced patients
 - No evidence of cirrhosis
- **Patient Groups**
 - N = 211 total received treatment
 - N = 44 Rx naïve with GT1: DCV+ SOF +/- RBV x 24 weeks
 - N = 44 Rx naïve patients with GT 2 or 3: DCV+ SOF +/- RBV x 24 weeks
 - N = 123 Rx naïve or experienced with GT 1: DCV+ SOF +/- RBV x 12 weeks
- **End-Points:** Primary = SVR12

Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3

A1444040 Design: Treatment-Naïve 24 Week Rx (Part 1)



Drug Dosing

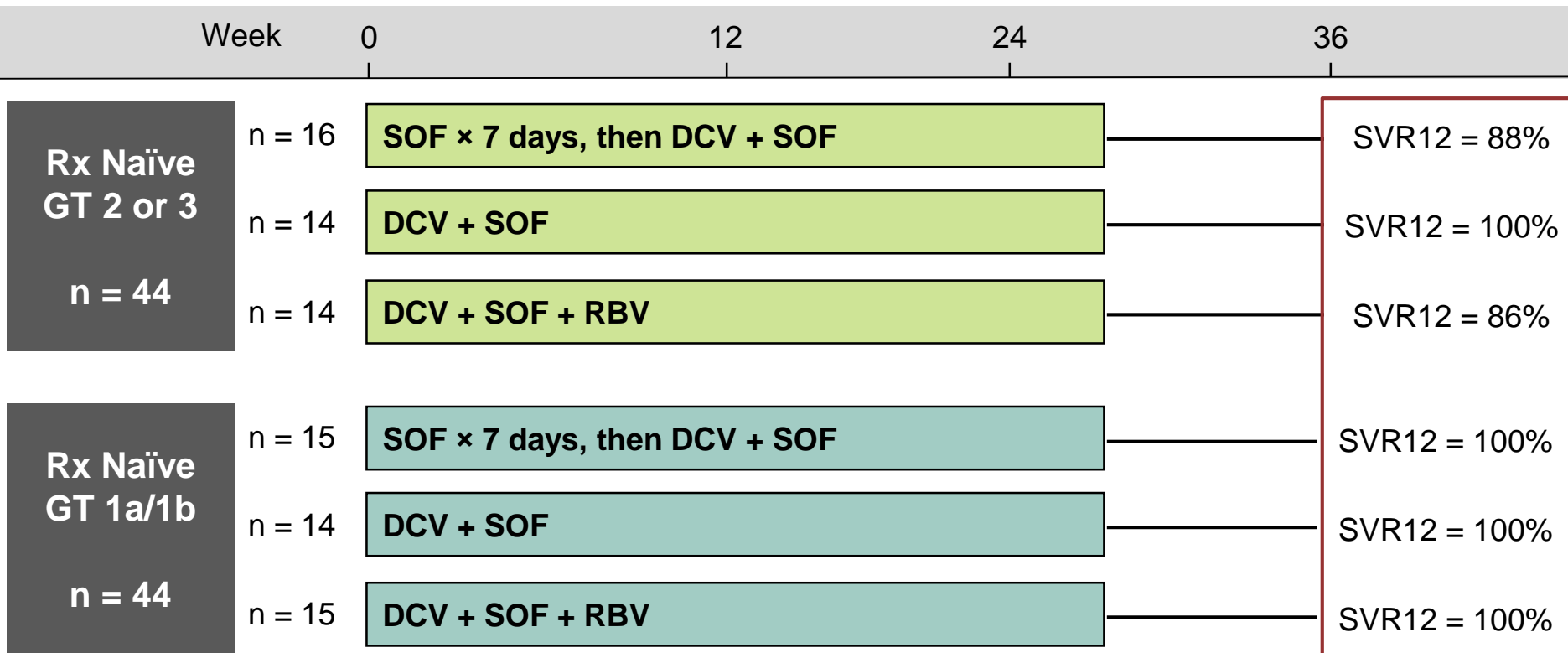
Daclatasvir (DCV): 60 mg once daily

Sofosbuvir (SOF): 400 mg once daily

Ribavirin (RBV): GT1, given weight-based and divided bid (1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg)

Ribavirin (RBV): GT 2,3 (800 mg/day)

Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3 Treatment-Naïve 24 Week Rx: Results (Part 1)



Drug Dosing

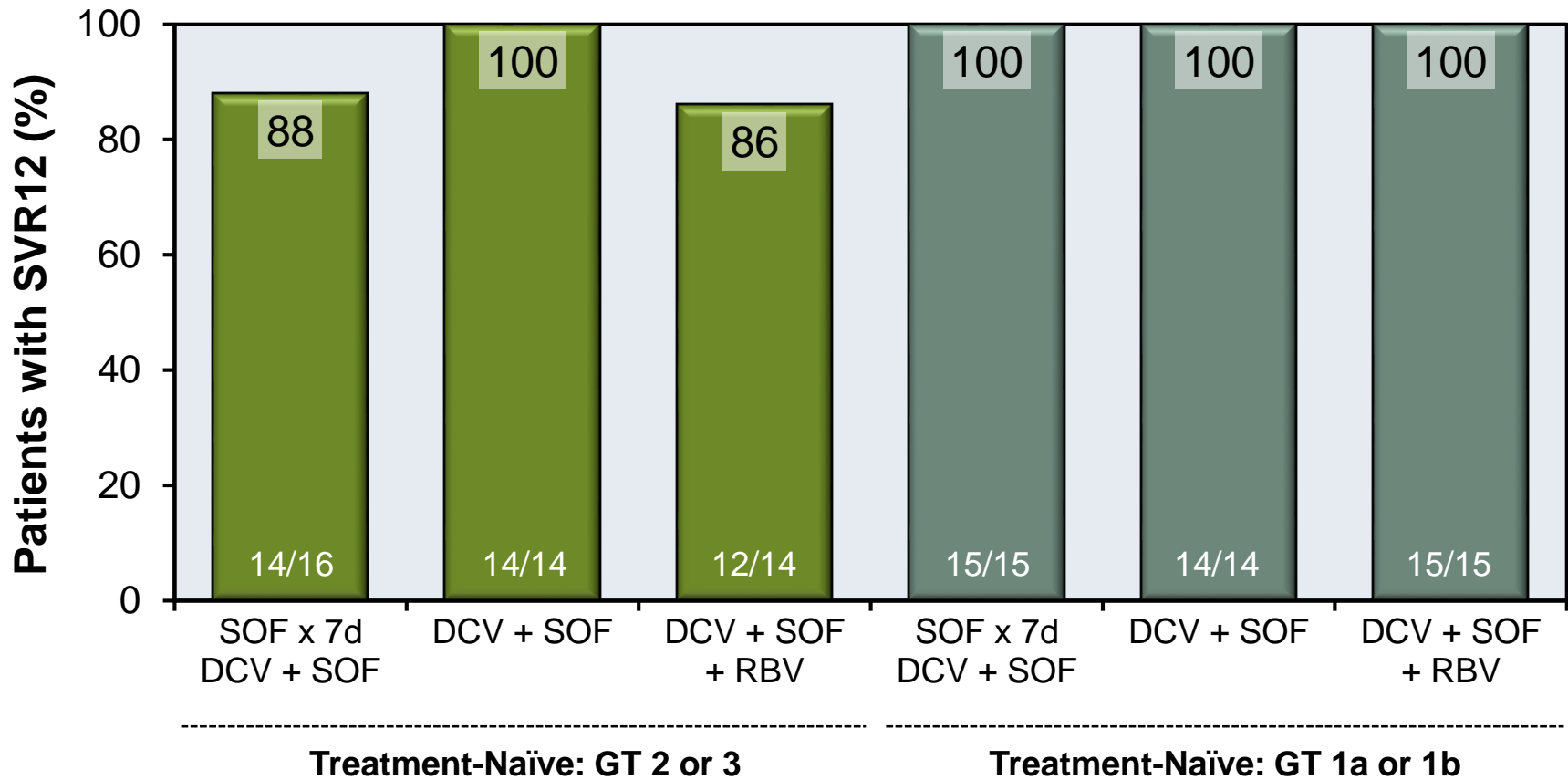
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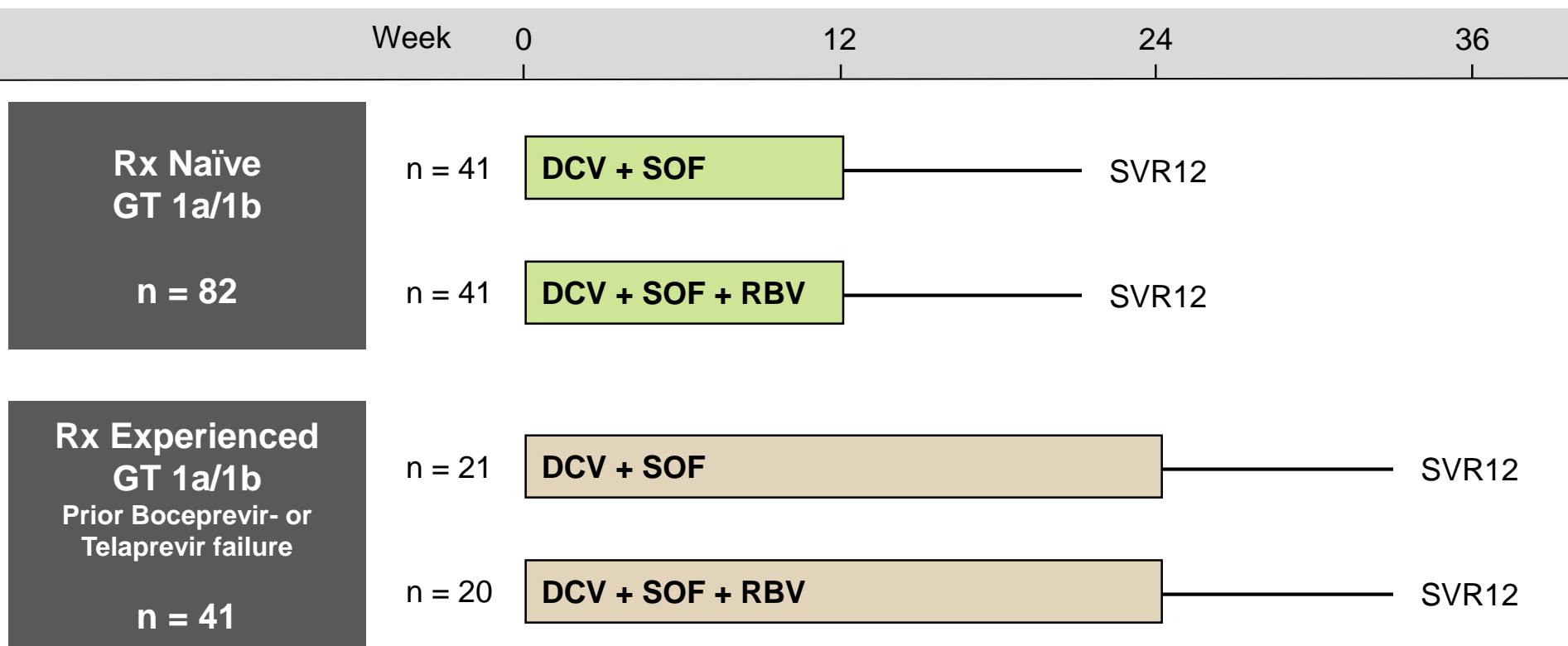
Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3 Treatment-Naïve 24 Week Rx: Results (Part 1)



DCV = daclatasvir; SOF = sofosbuvir; RBV = ribavirin

Source: Sulkowski MS, et al. N Engl J Med. 2014;370:211-21.

Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3 A1444040 Design: GT1 Treatment-Naïve & Experienced (Part 2)



Drug Dosing

Daclatasvir (DCV): 60 mg once daily

Sofosbuvir (SOF): 400 mg once daily

Ribavirin (RBV): GT1, given weight-based and divided bid (1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg)

Ribavirin (RBV): GT 2,3 (800 mg/day)

Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3 GT1 Treatment-Naïve & Experienced: Results (Part 2)

Week 0 12 24 36

Rx Naïve
GT 1a/1b

n = 82

n = 41

DCV + SOF

SVR12 = 100%

n = 41

DCV + SOF + RBV

SVR12 = 95%

Rx Experienced
GT 1a/1b

Prior Boceprevir- or
Telaprevir failure

n = 41

n = 21

DCV + SOF

SVR12 = 100%

n = 20

DCV + SOF + RBV

SVR12 = 95%

Drug Dosing

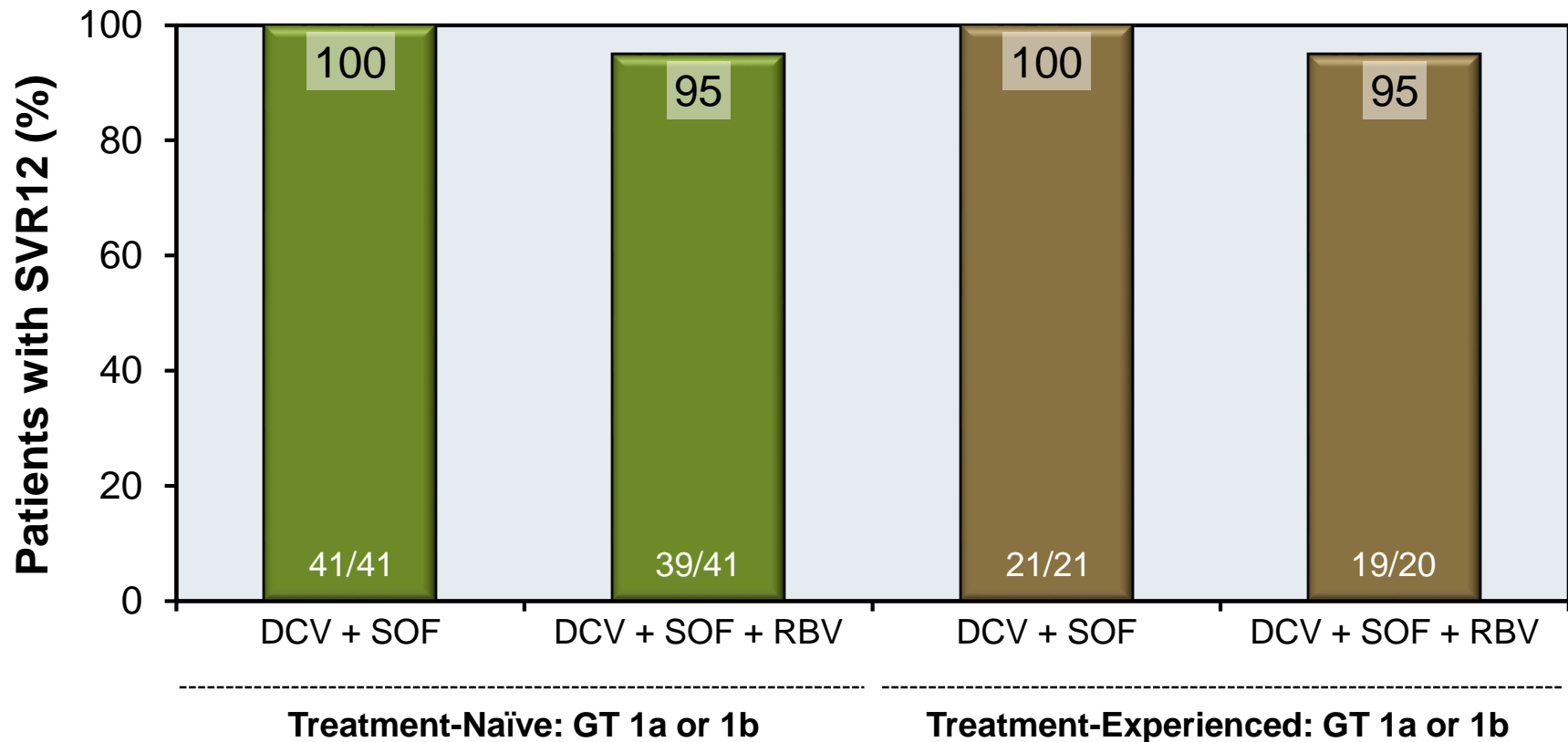
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Sofosbuvir (SOF): 400 mg once daily

Ribavirin (RBV): GT1, given weight-based and divided bid (1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg)

Ribavirin (RBV): GT 2,3 (800 mg/day)

Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1-3 GT1 Treatment-Naïve & Experienced: Results (Part 2)



DCV = daclatasvir; SOF = sofosbuvir; RBV = ribavirin

Source: Sulkowski MS, et al. N Engl J Med. 2014;370:211-21.

Daclatasvir + Sofosbuvir +/- Ribavirin for HCV GT 1 Trial: Conclusions

Conclusions: “Once-daily oral daclatasvir plus sofosbuvir was associated with high rates of sustained virologic response among patients infected with HCV genotype 1, 2, or 3, including patients with no response to prior therapy with telaprevir or boceprevir.”

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Hepatitis C Online

www.hepatitisc.uw.edu

Hepatitis Web Study

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

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