

Treatment Experienced

# Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6 C-EDGE Treatment Experienced (TE)

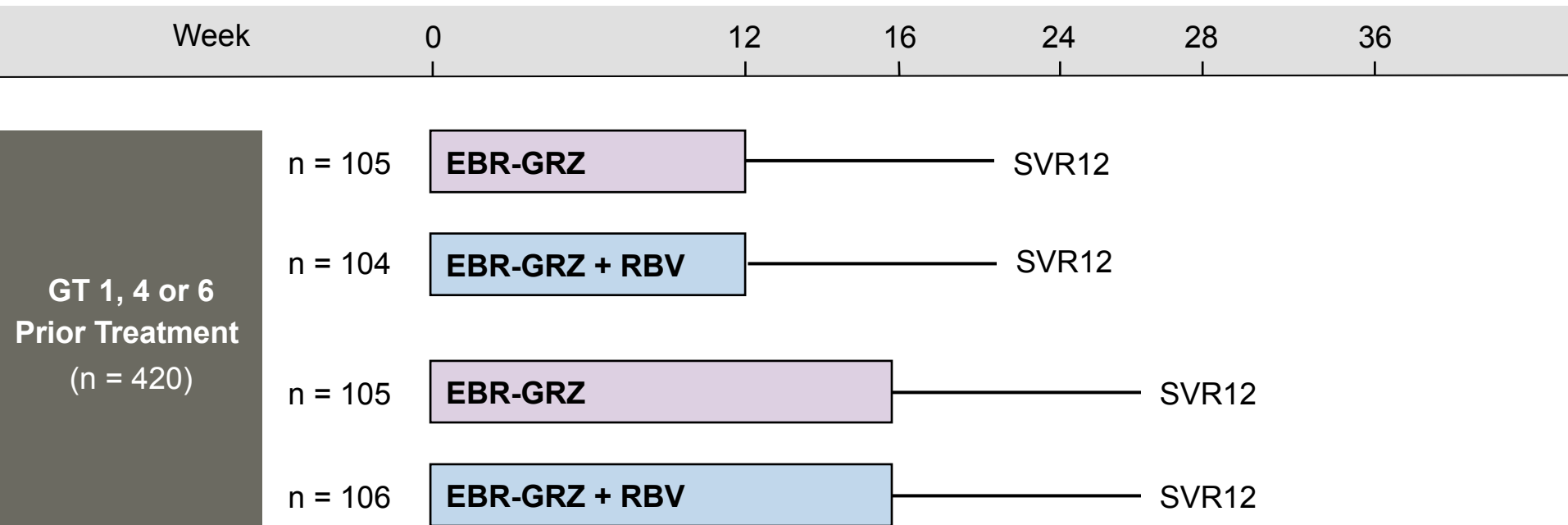
Source: Kwo P, et al. Gastroenterology. 2017;152:164-75.

# Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6 C-EDGE TE Study: Features

## C-EDGE TE Trial

- **Design:** Randomized, open label, parallel-group, phase 3 trial examining the safety and efficacy of a fixed-dose combination of elbasvir-grazoprevir with or without ribavirin for 12 or 16 weeks in treatment-experienced adults with GT 1, 4, or 6 HCV and previous failure of peginterferon plus ribavirin
- **Entry Criteria**
  - Chronic HCV Genotype 1, 4 or 6
  - 18 years or older
  - HCV RNA  $\geq 10,000$  IU/mL
  - History of peginterferon plus ribavirin treatment failure
  - Patients with compensated cirrhosis accepted
  - Some patients with HIV infection accepted
- **Primary End-Point:** SVR12

# Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6 C-EDGE TE: Study Design



**Abbreviations:** EBR-GZR = elbasvir-grazoprevir; RBV = ribavirin

## Drug Dosing

Elbasvir-grazoprevir (50/100 mg): fixed dose combination; one pill once daily

Ribavirin (weight-based and divided bid): 800 to 1400 mg/day

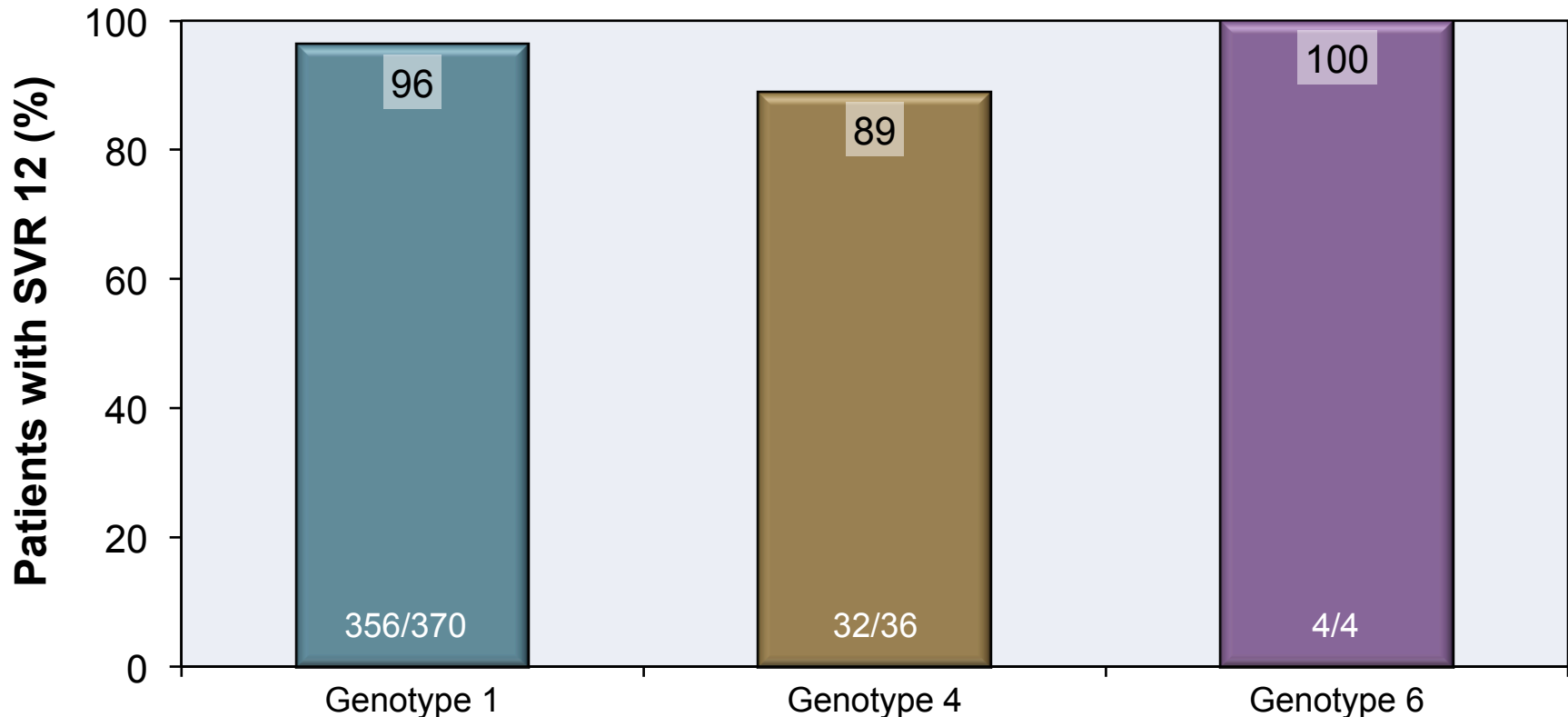
# Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6 C-EDGE TE: Baseline Characteristics

Baseline Characteristic	12-Week Treatment		16-Week Treatment	
	EBR-GRZ n=105	EBR-GRZ + RBV n=104	EBR-GRZ n=105	EBR-GRZ + RBV n=106
Age, y median (range)	56 (25–76)	56 (23–75)	55 (31–73)	55 (19–77)
Male sex, %	63	69	66	60
Race, n (%)				
Caucasian	66 (63)	70 (67)	72 (69)	78 (74)
African American	23 (22)	24 (23)	9 (9)	15 (14)
Asian	15 (14)	9 (9)	22 (21)	10 (9)
HCV Genotype, %				
1a	61 (58)	60 (58)	48 (46)	58 (55)
1b	34 (32)	29 (28)	48 (46)	36 (34)
4	9 (9)	15 (14)	5 (5)	8 (8)
6	0 (0)	0 (0)	4 (4)	2 (2)
Cirrhosis, %	37 (35)	35 (34)	38 (36)	37 (35)
HIV coinfection, %	6 (6)	5 (5)	6 (6)	4 (4)
Prior treatment response				
Relapse, %	35 (33)	38 (37)	38 (36)	40 (38)
Partial response, %	21 (20)	22 (21)	21 (20)	23 (22)
Prior null, %	49 (47)	44 (42)	46 (44)	43 (41)

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# Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6 C-EDGE TE: Results

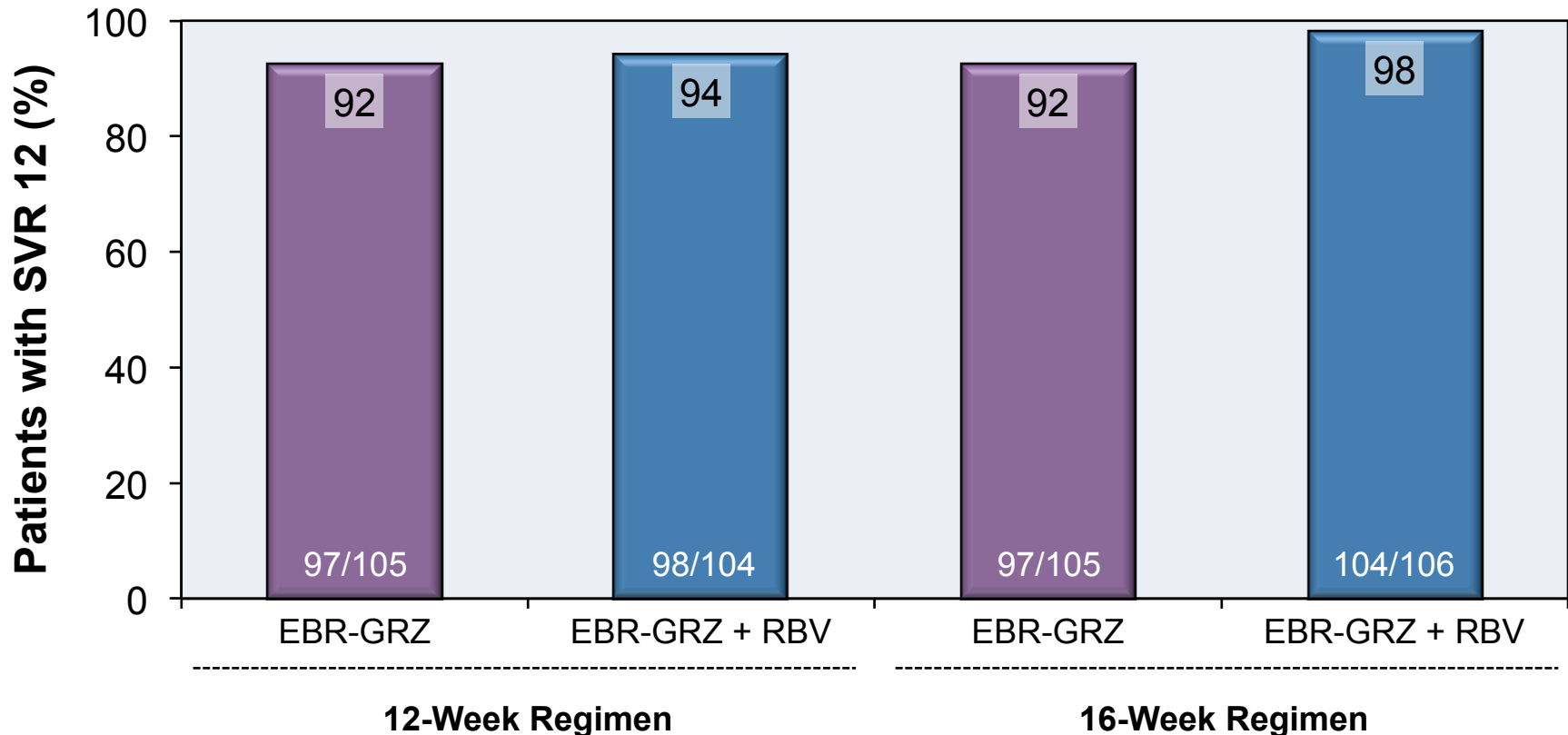
C-EDGE TE: SVR 12\*, by Genotype



\* Analysis per protocol: excluding patients who dropped out due to reasons other than virologic failure

# Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6 C-EDGE TE: Results

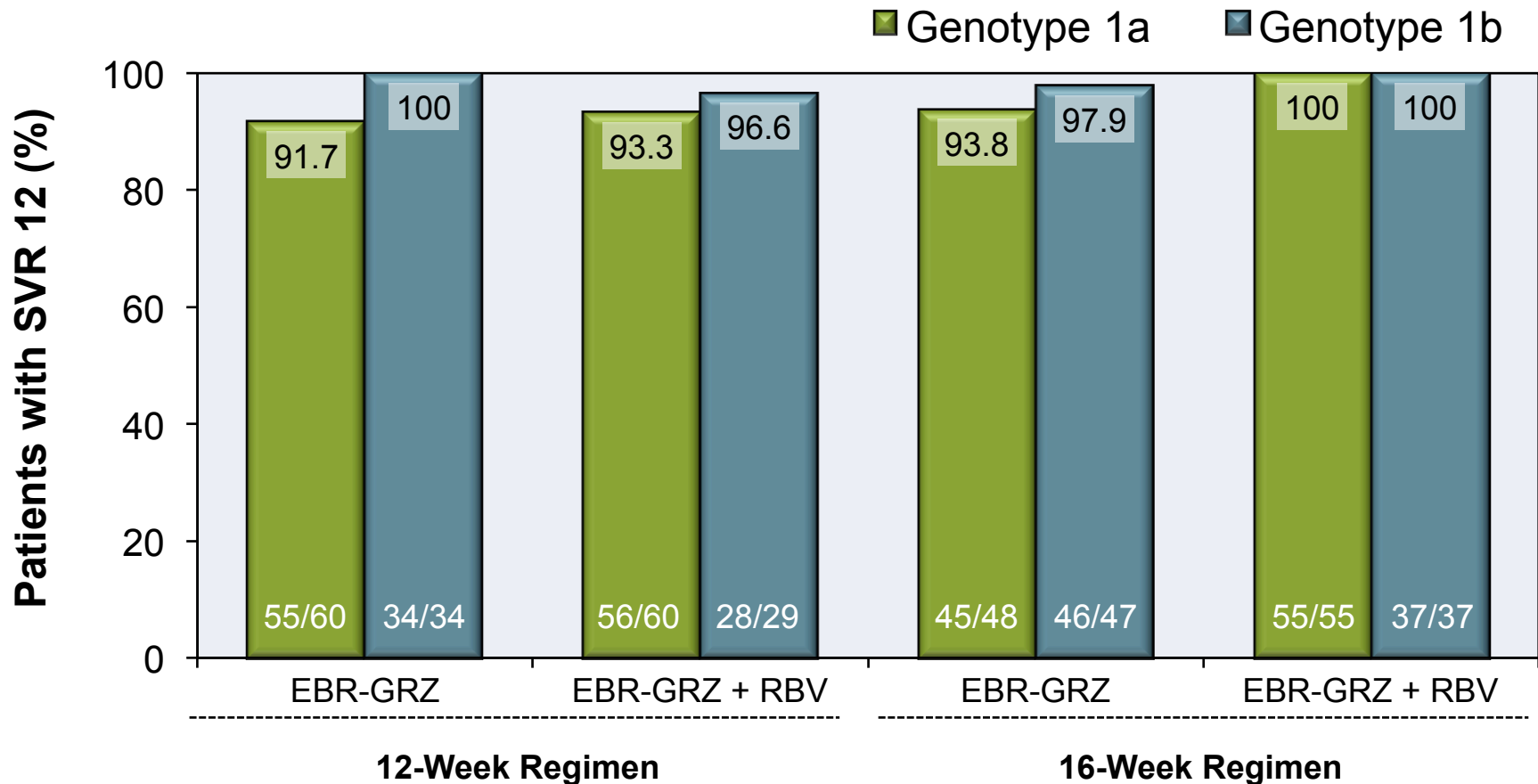
C-EDGE TE: SVR 12\* by Regimen and Treatment Duration (GT 1, 4, or 6)



\* Analysis per protocol: excluding patients who dropped out due to reasons other than virologic failure

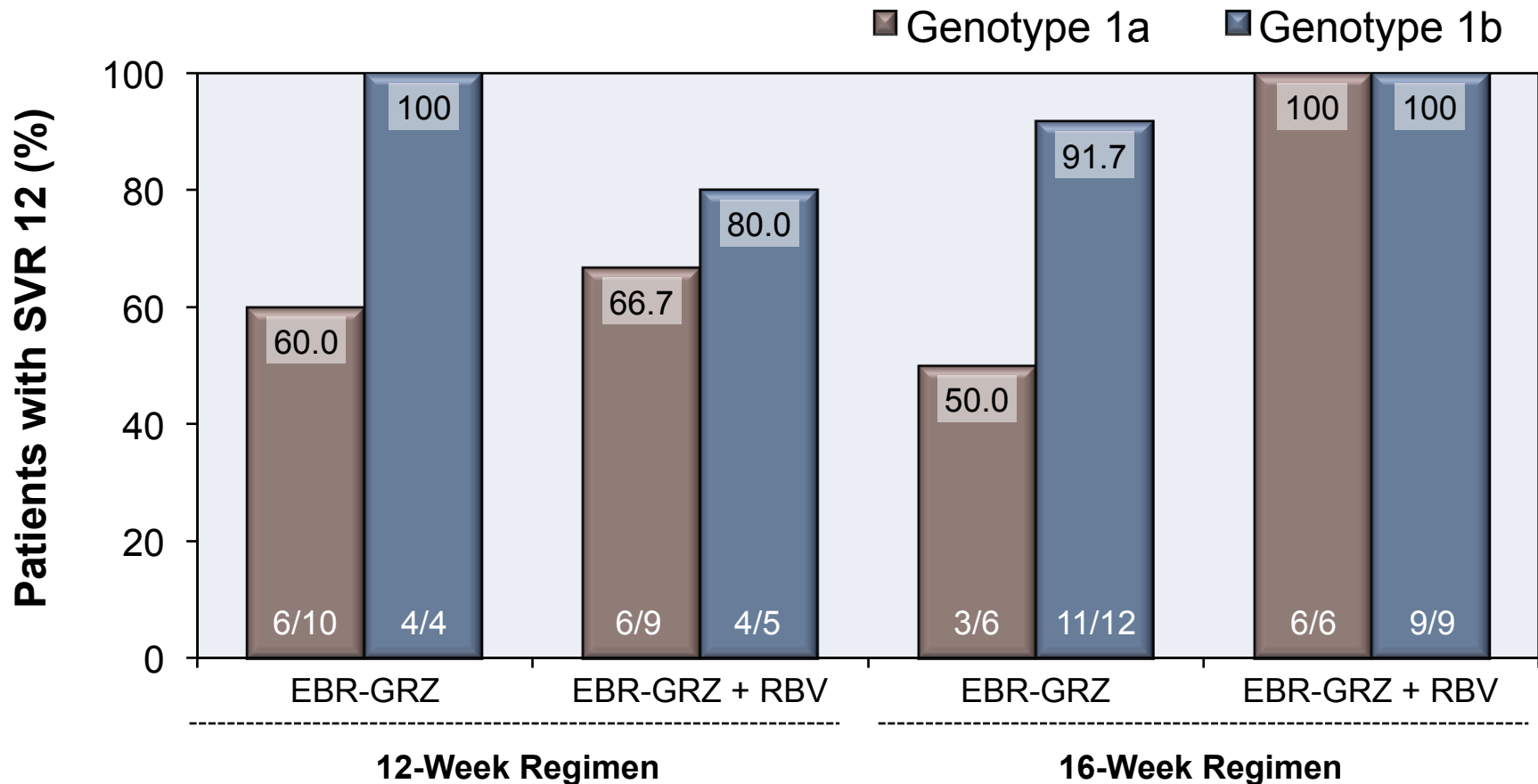
# Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6 C-EDGE TE: Results

C-EDGE TE: SVR 12 by Regimen, Treatment Duration, and GT1 Subtype



# Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6 C-EDGE TE: Results

C-EDGE TE: SVR 12 in Patients with Baseline NS5A RAVs



# Elbasvir-Grazoprevir +/- Ribavirin in HCV Genotype 1, 4 or 6 C-EDGE TE: Results

**Conclusions:** “The combination tablet of elbasvir and grazoprevir, with or without ribavirin, was highly efficacious in inducing an SVR12 in patients with HCV genotype 1, 4, or 6 infection failed by previous treatment with peg-interferon and ribavirin, including patients with cirrhosis and/or a prior null response. The treatment was generally well tolerated.”

This slide deck is from the University of Washington's *Hepatitis C Online* and *Hepatitis Web Study* projects.

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[www.hepatitisc.uw.edu](http://www.hepatitisc.uw.edu)

Hepatitis Web Study  
<http://depts.washington.edu/hepstudy/>

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