

Elbasvir-Grazoprevir in Persons with Compensated Cirrhosis Integrated Analysis

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Integrated Analysis: Study Features

- **Design:** Integrated analysis of data from six phase 2/3 trials of elbasvir-grazoprevir with or without ribavirin in patients with compensated cirrhosis: C-SURFER, C-EDGE COINFECTION, C-EDGE (NAÏVE & EXPERIENCED), C-WORTHY and C-SALVAGE
- **Entry Criteria**
 - Chronic HCV Genotype 1, 4, or 6
 - Child Pugh class A compensated cirrhosis
 - No prior treatment or treatment with peginterferon + ribavirin +/- 1st generation protease inhibitor (boceprevir, telaprevir, simeprevir)
 - 18 years or older
 - HCV RNA $\geq 10,000$ IU/mL
 - HIV infection allowed
- **Primary End-Point:** SVR12

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Integrated Analysis: Baseline Characteristics

Baseline Characteristic, n (%)	Elbasvir-Grazoprevir	
	Treatment Naïve (n = 169)	Treatment Experienced (n = 233)
Male	113 (67)	151 (65)
Age, y, mean (range)	56 (32-82)	57 (19-76)
Race		
White	131 (77.5)	193 (83)
Black	16 (9.5)	21 (9)
Asian	17 (10)	19 (8)
Other	5 (3)	0
Latinx	11 (6.5)	21 (9)
HCV genotype 1a	96 (57)	123 (53)
HCV genotype 1b or other	67 (41)	90 (39)
HCV genotype 4	6 (4)	17 (7)
HCV genotype 6	0	3 (1)
IL28B CC genotype	63 (37)	32 (14)
BMI ≥30 kg/m ²	34 (20)	68 (29)

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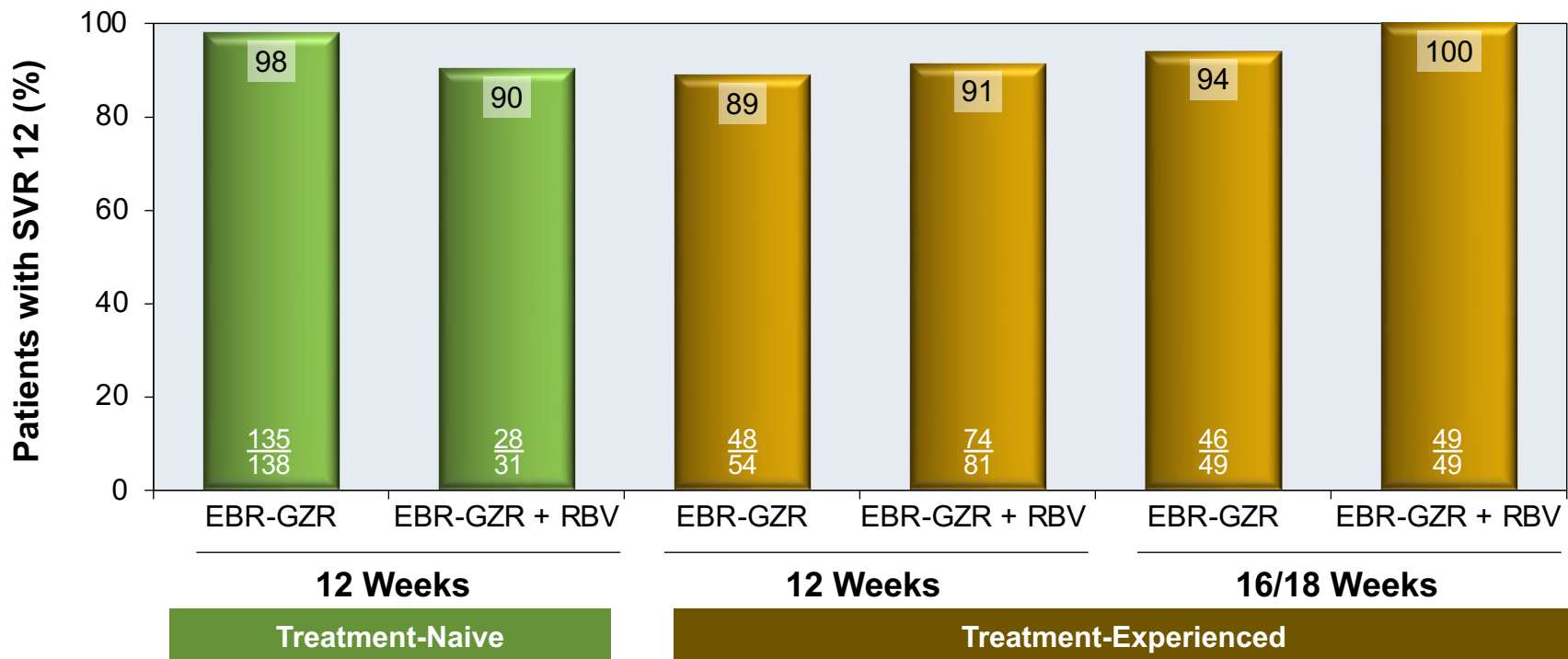
Integrated Analysis: Baseline Characteristics

Baseline Characteristic, n (%)	Elbasvir-Grazoprevir	
	Treatment Naïve (n = 169)	Treatment Experienced (n = 233)
HIV coinfection	35 (21)	5 (2)
Chronic kidney disease, stage 4 or 5	4 (2.4)	3 (1.3)
Prior treatment response		
Null	NA	120 (51.5)
Relapse	NA	59 (25)
Prior DAA	NA	34 (14.6)
Platelet count <100 x 10 ³ /μL	40 (24)	61 (26)
Albumin <3 g/dL	0	1 (0.4)
Cirrhosis determination method		
Biopsy	43 (25)	72 (31)
ALT-platelet ratio index + FibroTest	12 (7)	17 (7)
FibroScan	114 (67.5)	144 (62)
12.6 – 15 kPa	33 (29)	35 (24)
15.1 – 20 kPa	40 (35)	33 (23)
20.1-25 kPa	10 (9)	14 (10)
>25 kPa	31 (27)	62 (43)

Source: Jacobson IM, et al. Gastroenterology. 2017;152:1372-82.e2.

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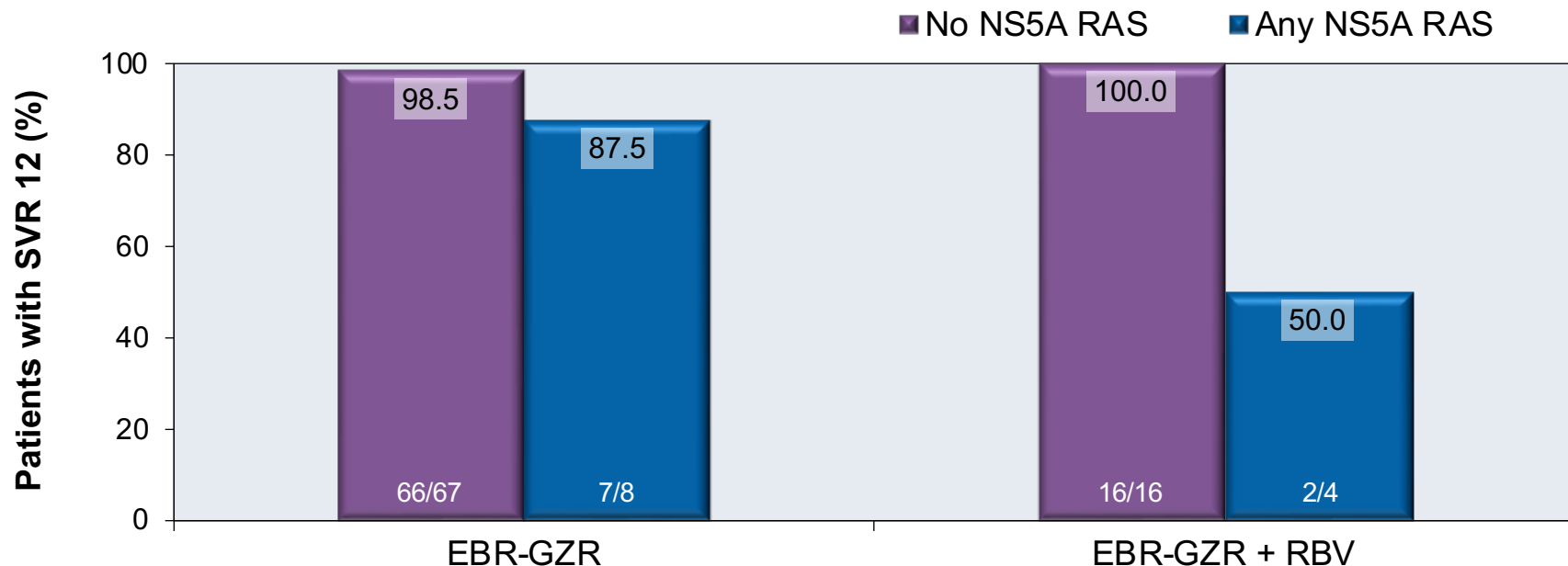
Integrated Analysis: Results



Abbreviations: EBR-GZR = elbasvir-grazoprevir; SOF = sofosbuvir; RBV = ribavirin

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Integrated Analysis: Treatment-Naïve

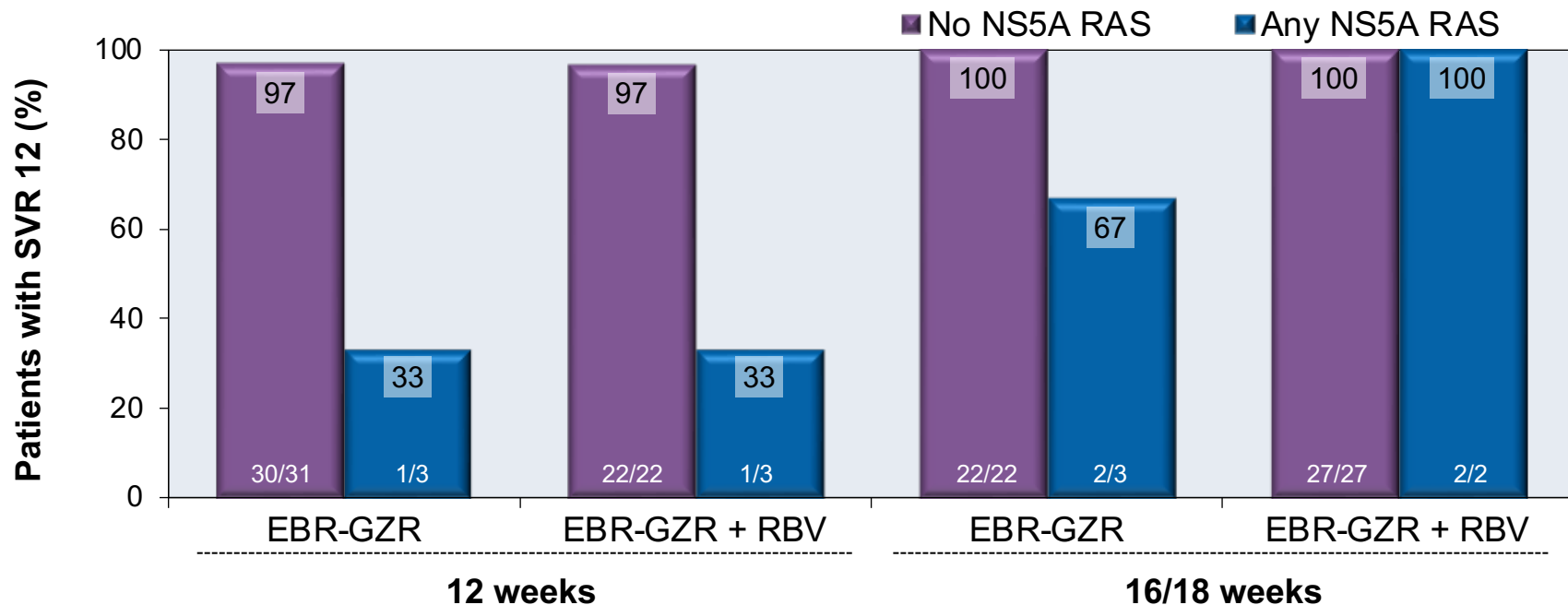


Abbreviations: RA = resistance-associated variant; EBR-GZR = elbasvir-grazoprevir; RBV = ribavirin

Note: RAS testing was via population-based sequencing with 25% threshold.

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Integrated Analysis: Treatment-Experienced



Abbreviations: RA = resistance-associated variant; EBR-GZR = elbasvir-grazoprevir; RBV = ribavirin

Note: RAS testing was via population-based sequencing with 25% threshold.

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Integrated Analysis: Conclusions

Conclusions: “In an analysis of data from 6 clinical trials, rates of SVR12 ranged from 89% to 100% in patients with HCV genotype 1, 4, or 6 infections and compensated cirrhosis treated with elbasvir/grazoprevir, with or without ribavirin. Addition of ribavirin to a 12-week regimen of elbasvir/grazoprevir had little effect on the proportion of treatment-naïve or treatment-experienced patients who achieved an SVR12.”

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