

Treatment Naïve

HIV Coinfection

Elbasvir-Grazoprevir in HCV and HIV Coinfection, GT 1, 4 or 6 C-EDGE CO-INFECTION

Rockstroh JK, et al. Lancet HIV. 2015;2:e319-27.

Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6

C-EDGE CO-INFECTION: Study Features

C-EDGE Trial

- **Design:** Prospective, open-label, single-arm study examining the safety and efficacy of a fixed-dose combination of elbasvir-grazoprevir for 12 weeks in treatment-naïve patients with chronic HCV genotype 1, 4, or 6 and HIV coinfection.
- **Entry Criteria**
 - Chronic HCV Genotype 1, 4, or 6
 - 18 years or older
 - HCV RNA $\geq 10,000$ IU/mL
 - No prior treatment
 - Compensated cirrhosis permitted
 - HIV infection
- **Primary End-Point:** SVR12

Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6 C-EDGE CO-INFECTION: Study Design

Week

0

12

24

HIV-HCV Coinfected
Treatment-naïve
GT 1, 4 or 6

N=218

Elbasvir-Grazoprevir

SVR12

Drug Dosing

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

Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6 C-EDGE CO-INFECTION: Participants

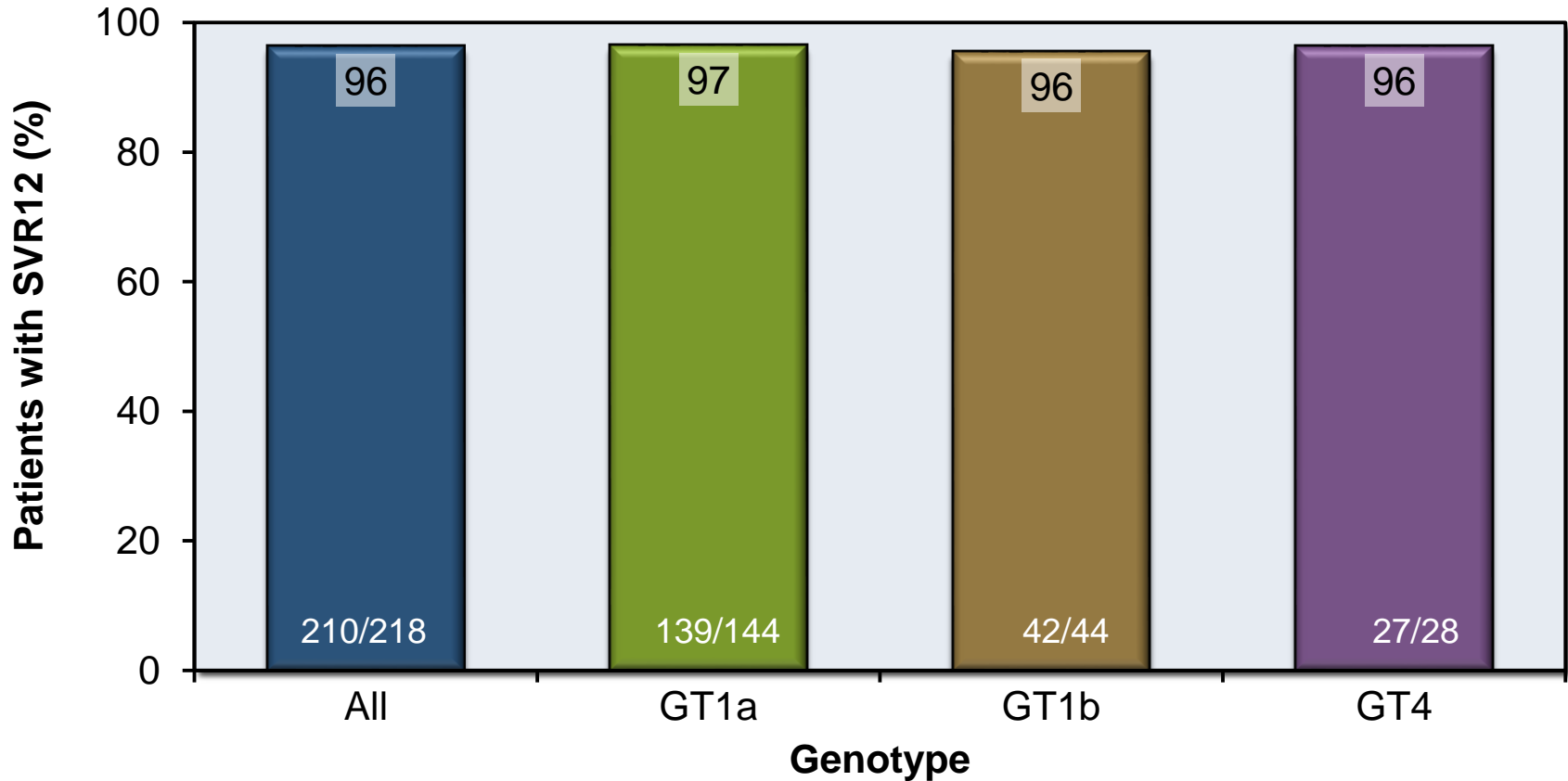
Baseline Characteristic	Elbasvir-Grazoprevir (N=218)
Age, mean	49
Male, n (%)	183 (84%)
Race, n (%)	
White	167 (77%)
Black or African-American	38 (17%)
Other	13 (6%)
HCV genotype, n (%)	
1a	144 (66%)
1b	44 (20%)
4	28 (13%)
6	2 (1%)
Fibrosis stage, n (%)	
F0-2	160 (73%)
F3	23 (11%)
F4	35 (16%)
Mean baseline HCV RNA, log ₁₀ IU/ml	6.03

Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6 C-EDGE CO-INFECTION: Participants

HIV Characteristics	Elbasvir-Grazoprevir (N=218)
Median CD4 cell count, (IQR)	568 (424-766)
ART Status	
On ART with undetectable HIV RNA	211 (97%)
ART naïve	7 (3%)
ART nucleos(t)ide pair	
Abacavir-containing	47 (22%)
Tenofovir-containing	164 (75%)
None	7 (3%)
ART Third Agent	
Raltegravir	113 (52%)
Dolutegravir	59 (27%)
Rilpivirine	38 (17%)
None	8 (4%)
IQR = interquartile range; ART = antiretroviral therapy	

Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6 C-EDGE CO-INFECTION: Results

C-EDGE CO-INFECTION: SVR12 Results by Genotype



Overall SVR12 results includes the 2 patients with GT 6, who both achieved SVR12.

Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6 C-EDGE CO-INFECTION: Adverse Events

Adverse Event (AE), n (%)	Elbasvir-Grazoprevir (N=218)	
Discontinuation due to AE	0	
Serious AEs	2 (1%)	
Deaths	0	
Any AE in >5% of patients		
Fatigue	29 (13%)	
Headache	27 (12%)	
Nausea	20 (9%)	
Upper respiratory tract infection	18 (8%)	
Diarrhea	16 (7%)	
Insomnia	15 (7%)	
Grade 3 or 4 laboratory abnormality	<u>Grade 3</u>	<u>Grade 4</u>
Total bilirubin	1 (<1%)	0
ALT elevation	3 (1%)	2 (1%)
AST elevation	0	1 (<1%)
Hemoglobin	0	0

Elbasvir-Grazoprevir in HCV-HIV Coinfection GT 1, 4 or 6 C-EDGE CO-INFECTION: Conclusions

Conclusions: “This HCV treatment regimen seems to be effective and well tolerated for patients co-infected with HIV with or without cirrhosis. These data are consistent with previous trials of this regimen in the monoinfected population. This regimen continues to be studied in phase 3 trials.”