Daclatasvir + Sofosbuvir in HCV GT 1-4 and HIV Coinfection

ALLY-2 Study

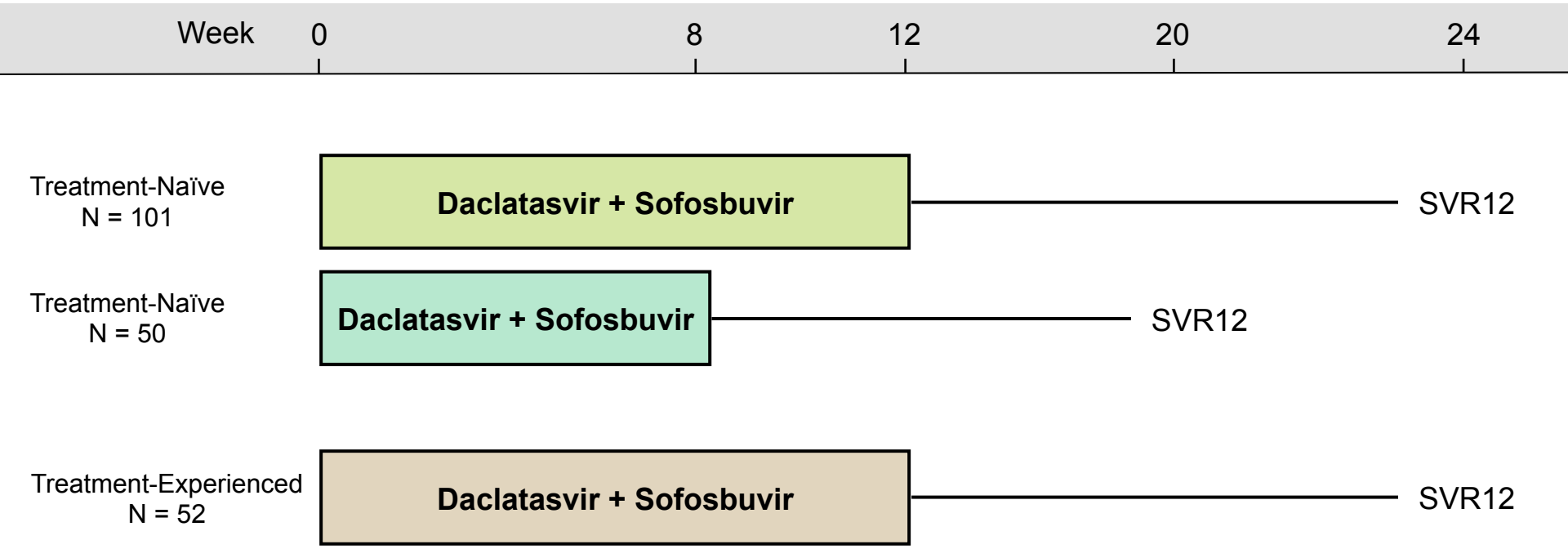
Daclatasvir + Sofosbuvir for HCV GT 1-4 and HIV Coinfection
ALLY-2 Trial: Study Features

ALLY-2: Features

- **Design**: Phase 3, open-label study of daclatasvir (DCV) plus sofosbuvir (SOF) in treatment-naïve or experienced, chronic HCV GT 1-4 and HIV coinfection
- **Setting**: Multiple centers in the United States
- **Entry Criteria**
  - N = 395 patients enrolled
  - Chronic HCV Genotype 1 through 4
  - Treatment-naïve or treatment experienced
  - Noncirrhotic or compensated cirrhosis (less than 50%)
  - Stable ARV with HIV RNA < 50 copies/ml at screening and <200 copies/ml for ≥8 weeks; and CD4 count > 100 cells/mm^3
  - ARVs allowed: tenofovir, emtricitabine, abacavir, lamivudine, zidovudine, darunavir-ritonavir, atazanavir-ritonavir, lopinavir-ritonavir, efavirenz, nevirapine, rilpivirine, dolutegravir, raltegravir, enfuvirtide, maraviroc
- **End-Points**: Primary = SVR12

Source: Wyles DL, et al. N Engl J Med. 2015;373:714-25.

Daclatasvir + Sofosbuvir for HCV GT 1-4 and HIV Coinfection
ALLY-2 Trial: Design



Drug Dosing

Daclatasvir: 60 mg once daily; with efavirenz and nevirapine the dose was increased to 90 mg once daily and with ritonavir-boosted protease inhibitors the dose was decreased to 30 mg once daily

Sofosbuvir: 400 mg once daily

Source: Wyles DL, et al. N Engl J Med. 2015;373:714-25.

Daclatasvir + Sofosbuvir for HCV GT 1-4 and HIV Coinfection
ALLY-2 Trial: Patient Characteristics

Characteristic	Treatment-Naïve 12-Week Group (n=101)	Treatment-Naïve 8-Week Group (n=50)	Previously Treated 12-Week Group (n=52)
Male, n (%)	92 (91%)	42 (84%)	43 (83%)
Median age, years (range)	52 (24-71)	51 (28-75)	57 (43-66)
Race White Black Asian/other	 66 (65%) 30 (30%) 5 (5%)	 28 (56%) 19 (38%) 3 (6%)	 31 (60%) 20 (38%) 1 (2%)
HCV genotype 1A 1B 2 3 4	 71 (70%) 12 (12%) 11 (11%) 6 (6%) 1 (1%)	 35 (70%) 6 (12%) 6 (12%) 3 (6%) 0	 33 (63%) 11 (21%) 2 (4%) 4 (8%) 2 (4%)
Cirrhosis	9 (9%)	5 (10%)	15 (29%)
Median HCV RNA $\log_{10}$ (IU/mL)(range)	6.7 (3.3-7.6)	6.4 (4.2-7.5)	6.7 (3.9-7.9)

Source: Wyles DL, et al. N Engl J Med. 2015;373:714-25.

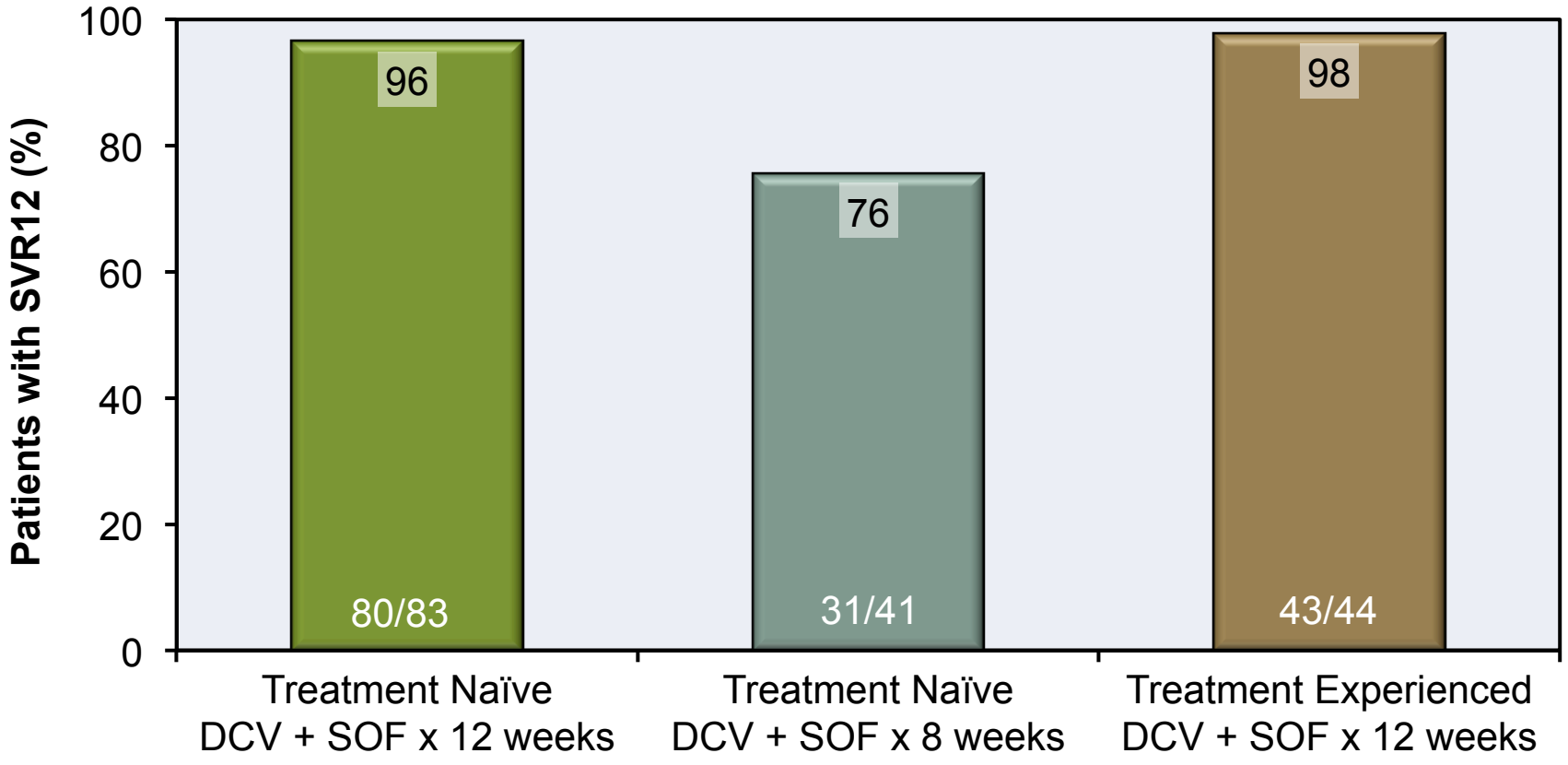
Daclatasvir + Sofosbuvir for HCV GT 1-4 and HIV Coinfection
ALLY-2 Trial: HIV Characteristics

Characteristic	Treatment-Naïve 12-Week Group (n=101)	Treatment-Naïve 8-Week Group (n=50)	Previously Treated 12-Week Group (n=52)
Median CD4 count (range) — cells/mm^3	520 (122-1147)	575 (157-1430)	636 (262-1470)
HIV-1 RNA <50 copies/ml	94/100 (94%)	45/48 (94%)	47/49 (96%)
Antiretroviral treatment, %	Total 99%	Total 96%	Total 98%
Darunavir-ritonavir	19%	44%	22%
Atazanavir-ritonavir	19%	10%	24%
Lopinavir-ritonavir	9%	6%	0
Efavirenz	18%	17%	16%
Nevirapine	5%	2%	6%
Rilpivirine	5%	2%	2%
Raltegravir	22%	17%	20%
Dolutegravir	3%	2%	8%
Nucleoside RTI only	0	0	4%

Source: Wyles DL, et al. N Engl J Med. 2015;373:714-25.

Daclatasvir + Sofosbuvir for HCV GT 1-4 and HIV Coinfection
ALLY-2 Trial: Results for Genotype 1

SVR12, Genotype 1

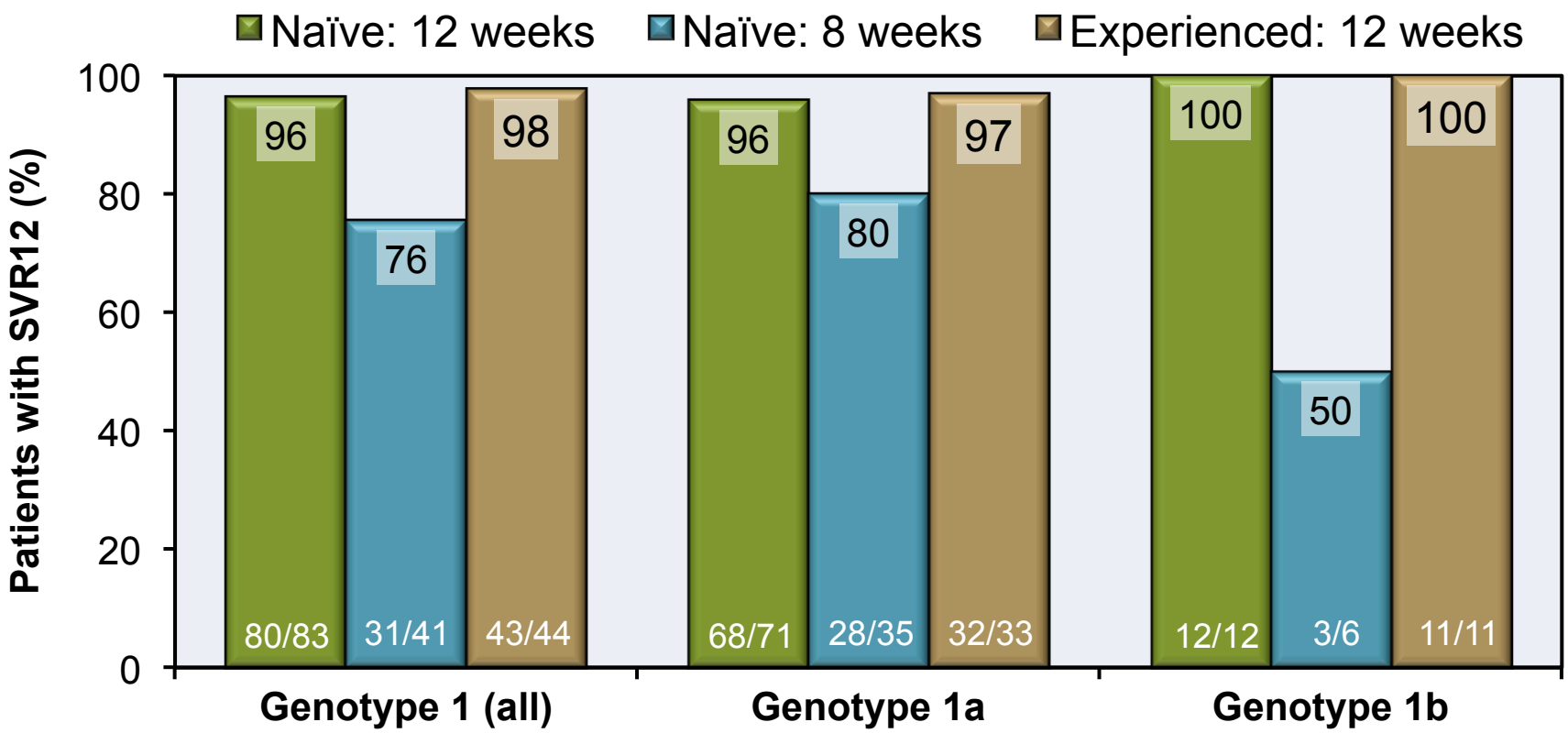


Abbreviations: DCV = daclatasvir; SOF = sofosbuvir

Source: Wyles DL, et al. N Engl J Med. 2015;373:714-25.

Daclatasvir + Sofosbuvir for HCV GT 1-4 and HIV Coinfection
ALLY-2 Trial: Results

SVR12, Genotype 1 and subtypes



n=11 had missing or inconclusive findings for cirrhosis & not included in denominators

Source: Wyles DL, et al. N Engl J Med. 2015;373:714-25.

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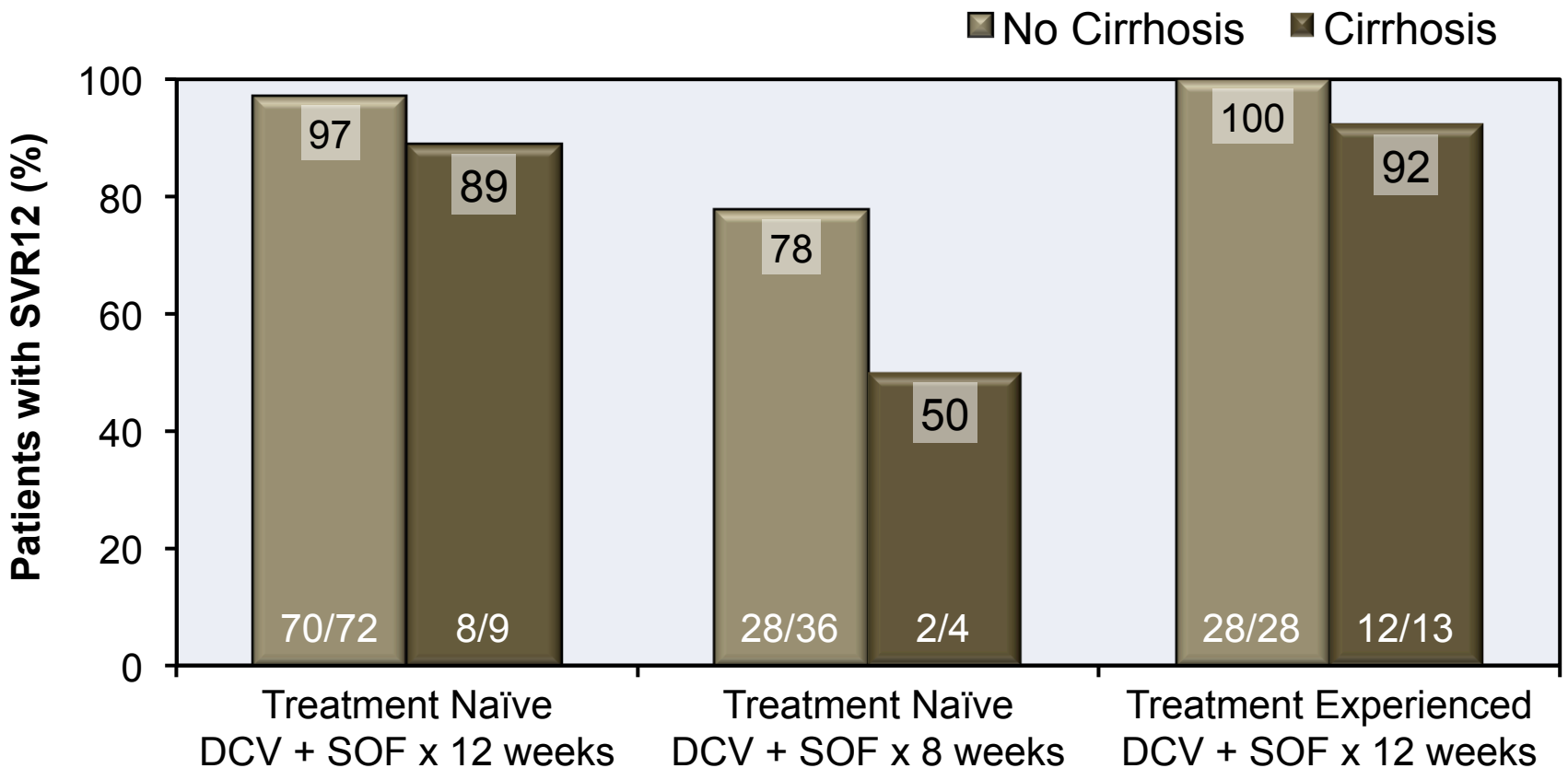
Daclatasvir + Sofosbuvir for HCV GT 1-4 and HIV Coinfection
ALLY-2 Trial: Results for Genotype 1

SVR12, Genotype 1, by Liver Status



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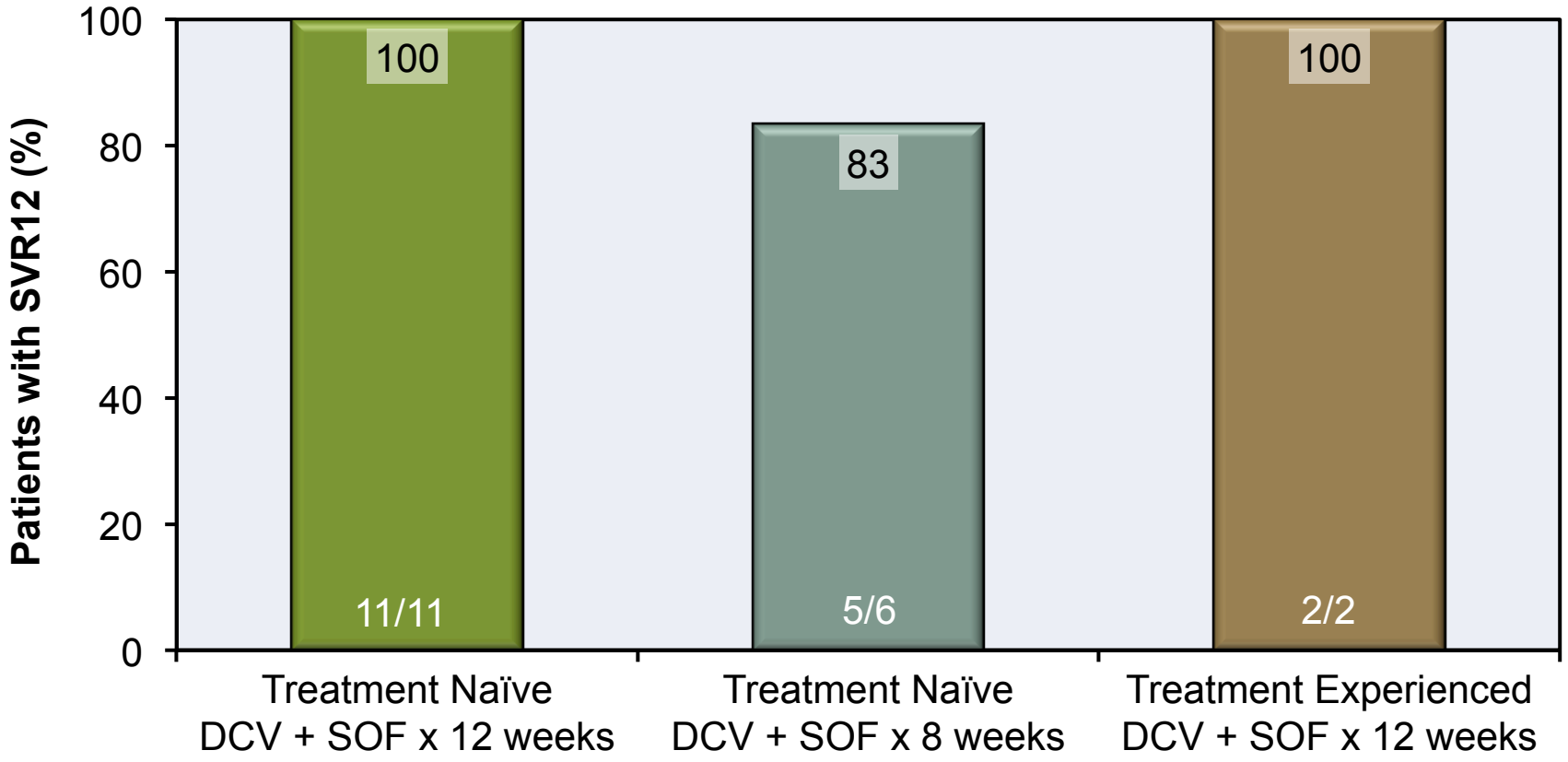
Source: Wyles DL, et al. N Engl J Med. 2015;373:714-25.

Daclatasvir + Sofosbuvir for HCV GT 1-4 and HIV Coinfection
ALLY-2 Trial: Results for Genotype 2

SVR12, Genotype 2



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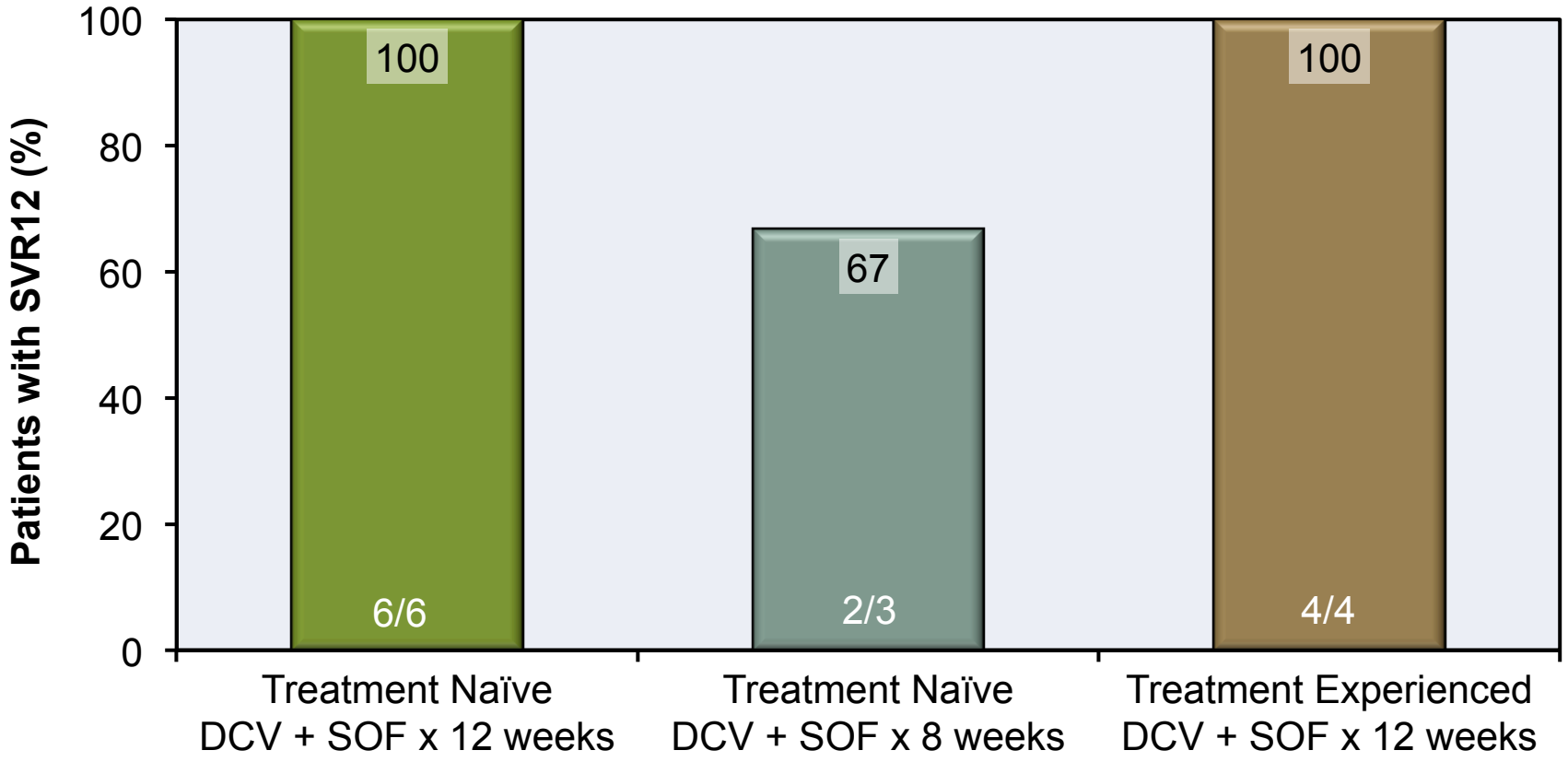
Source: Wyles DL, et al. N Engl J Med. 2015;373:714-25.

Daclatasvir + Sofosbuvir for HCV GT 1-4 and HIV Coinfection
ALLY-2 Trial: Results for Genotype 3

SVR12, Genotype 3



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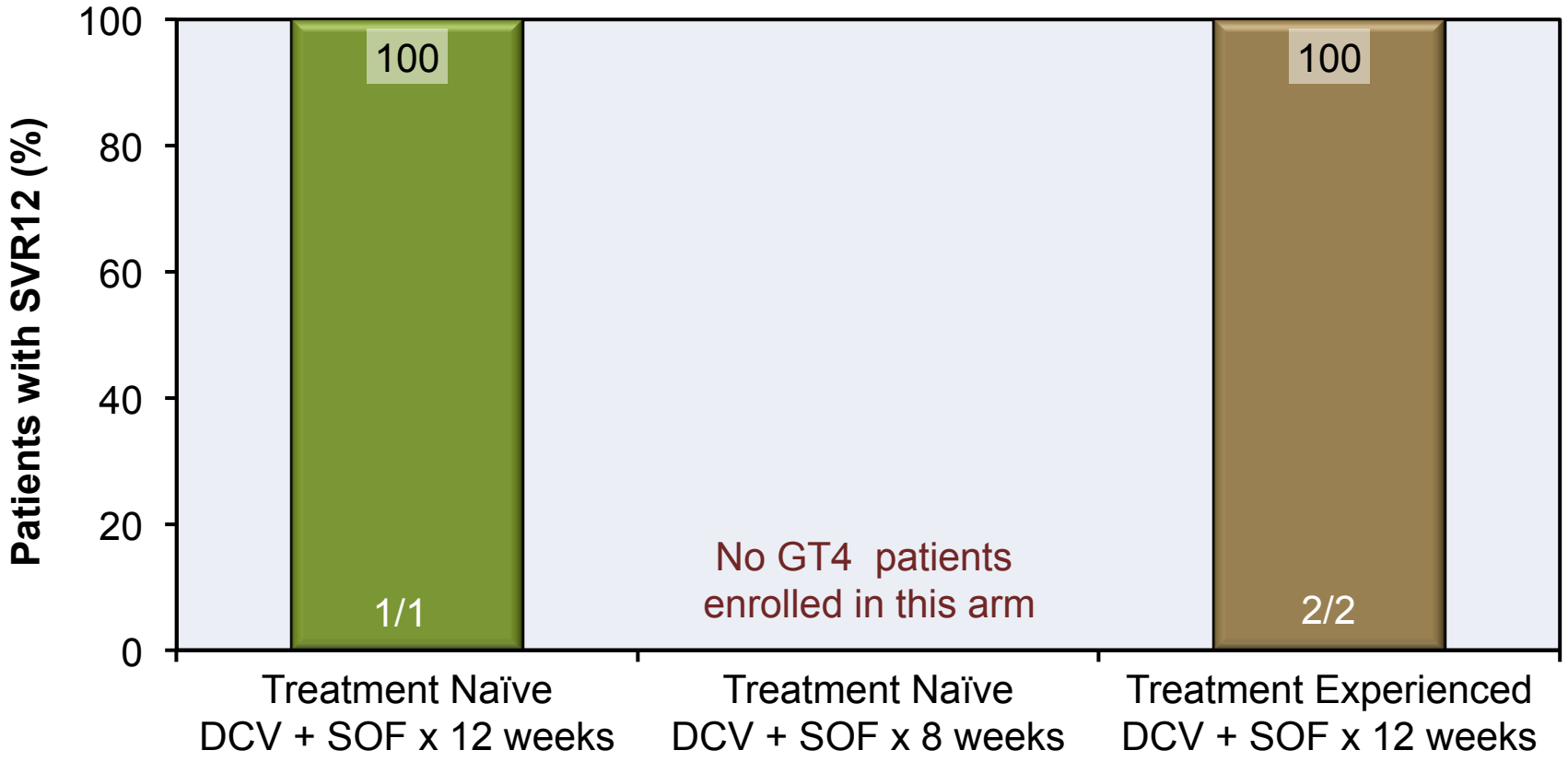
Daclatasvir + Sofosbuvir for HCV GT 1-4 and HIV Coinfection
ALLY-2 Trial: Results for Genotype 4

SVR12, Genotype 4



Abbreviations: DCV = daclatasvir; SOF = sofosbuvir

Source: Wyles DL, et al. N Engl J Med. 2015;373:714-25.

Daclatasvir + Sofosbuvir for HCV GT 1-4 and HIV Coinfection
ALLY-2 Trial: Conclusion

Conclusion: “Among previously untreated HIV–HCV coinfected patients receiving daclatasvir plus sofosbuvir for HCV infection, the rate of sustained virologic response across all genotypes was 97.0% after 12 weeks of treatment and 76.0% after 8 weeks.”

Source: Wyles DL, et al. N Engl J Med. 2015;373:714-25.

Acknowledgment

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AETC AIDS Education & Training Center Program
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