Phase 3

Treatment Naïve & Experienced

HIV Coinfection

Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients
ASTRAL-5

Wyles D, et al. Clin Infect Dis. 2017 March 29. [Epub ahead of print]

Hepatitis web study

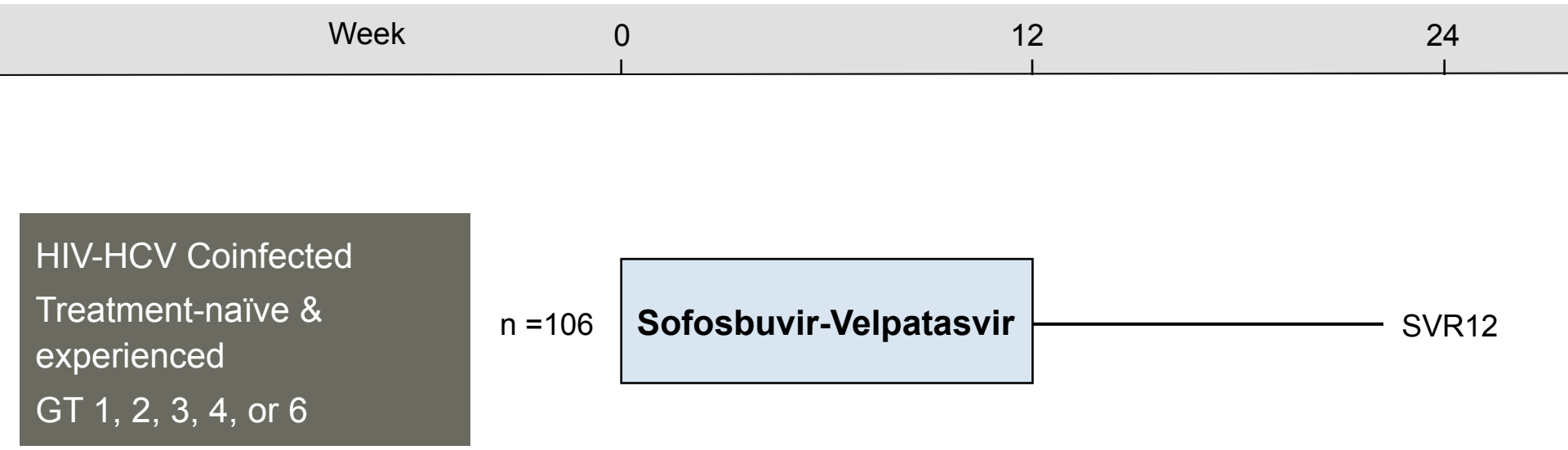
Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients
ASTRAL-5: Study Features

ASTRAL-5 Trial

- **Design**: Single-arm, open-label, multicenter, phase 3 trial of sofosbuvir-velpatasvir in HIV-HCV coinfected treatment-naïve and treatment-experienced patients with genotypes 1-6 HCV
- **Setting**: Multiple sites in US
- **Entry Criteria**
  - Chronic HCV GT 1-6
  - Age ≥18 years
  - HIV coinfection and on stable ART for ≥ 8 weeks
  - CD4 count ≥100 cells/mm^3 and HIV RNA ≤50 copies/mL
  - On stable ART for ≥ 8 weeks
  - Prior treatment failure allowed (but no prior NS5A or NS5B)
  - Patients with compensated cirrhosis allowed
- **Primary End-Point**: SVR12

Source: Wyles D, et al. Clin Infect Dis. 2017 March 29. [Epub ahead of print]

Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients
ASTRAL-5: Study Design



Drug Dosing: Sofosbuvir-velpatasvir (400/100 mg): fixed-dose combination; one pill once daily

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Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients
ASTRAL-5: Participants

Baseline Characteristic	**Sofosbuvir-Velpatasvir** (N=106)
Age, mean, years (range)	54 (25-72)
Male, n (%)	91 (86)
Black race, n (%)	48 (45)
HCV genotype, n (%) 1a 1b 2 3 4	 66 (62) 12 (11) 11 (10) 12 (11) 5 (5)
IL28B non-CC, n (%)	82 (77)
Mean HCV RNA, $\log_{10}$ IU/ml (range)	6.3 (5.0-7.4)
Cirrhosis, n (%)	19 (18)
Treatment experienced, n (%)	31 (29)

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Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients
ASTRAL-5: Participants

HIV Baseline Characteristics	**Sofosbuvir-Velpatasvir** (N=106)
Mean CD4 cell count, (range)	598 (183-1513)
Nucleos(t)ide pair	
TDF with boosted agent (RTV or Cobi)	56 (53)
TDF without boosted agent	35 (33)
Abacavir-lamivudine	15 (14)
Other antiretroviral agent(s)	
PI (DRV, LPV or ATV)	50 (47)
NNRTI (RPV)	13 (12)
Integrase inhibitor (RAL or EVG)	36 (34)
Other (>1 of above classes)	7 (7)

Abbreviations: TDF = Tenofovir disoproxil fumarate; RTV = ritonavir; Cobi = cobicistat; PI = HIV protease inhibitor; DRV = darunavir; LPV = lopinavir; ATV = atazanavir; PRV = rilpivirine; RAL = raltegravir; EVG = elvitegravir

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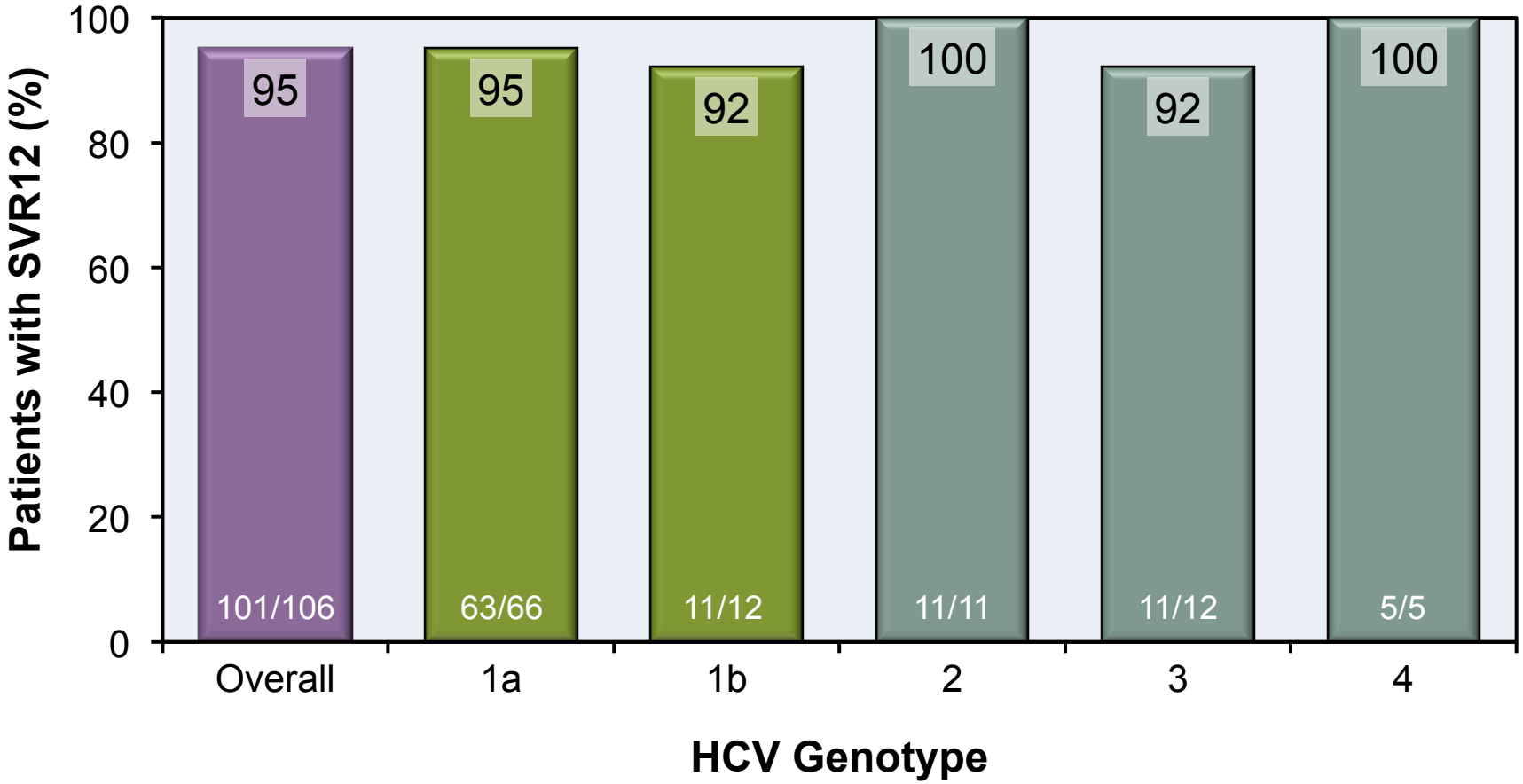
Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients
ASTRAL-5: Results

ASTRAL-5: SVR12 Results by Genotype



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ASTRAL-5: Results

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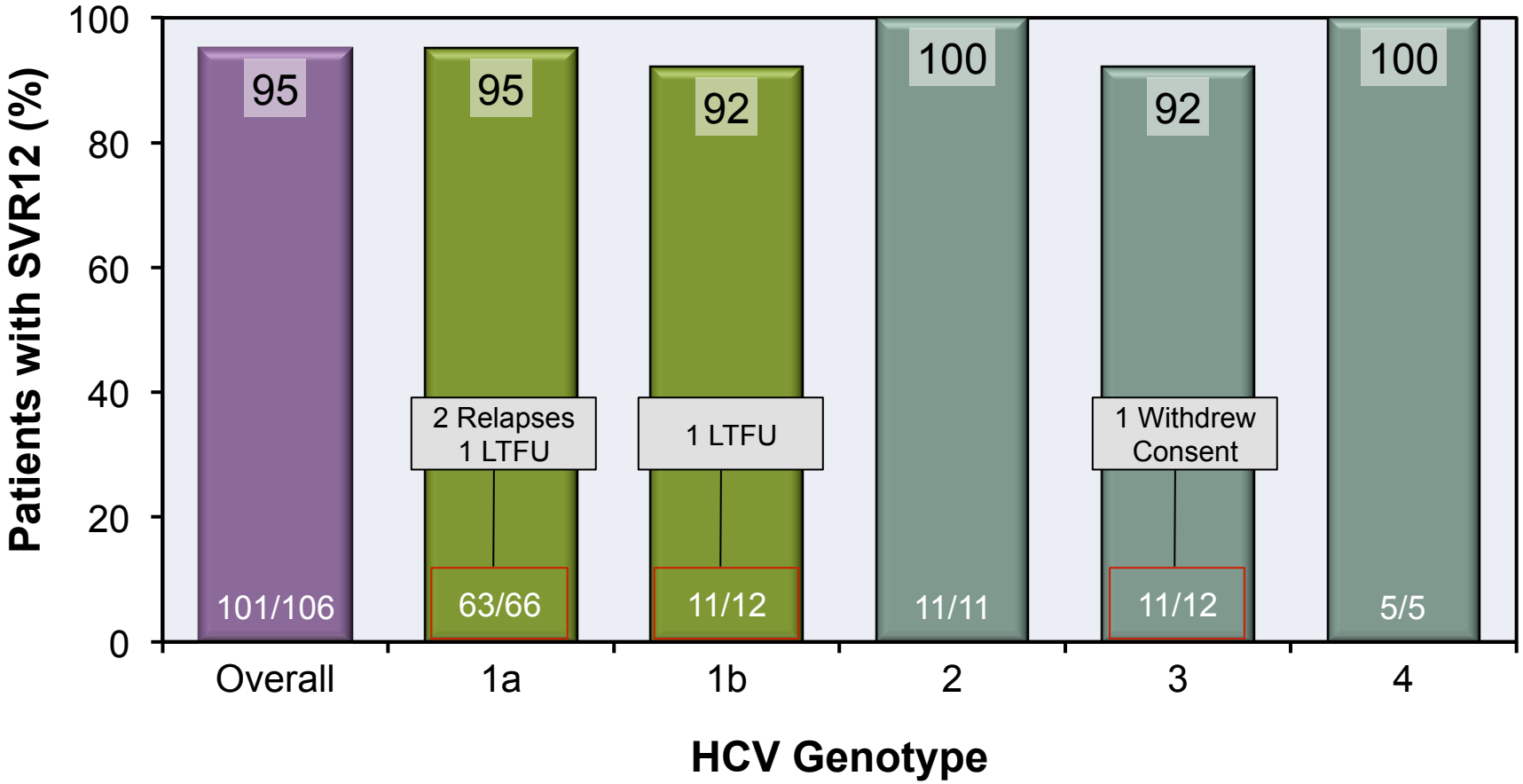

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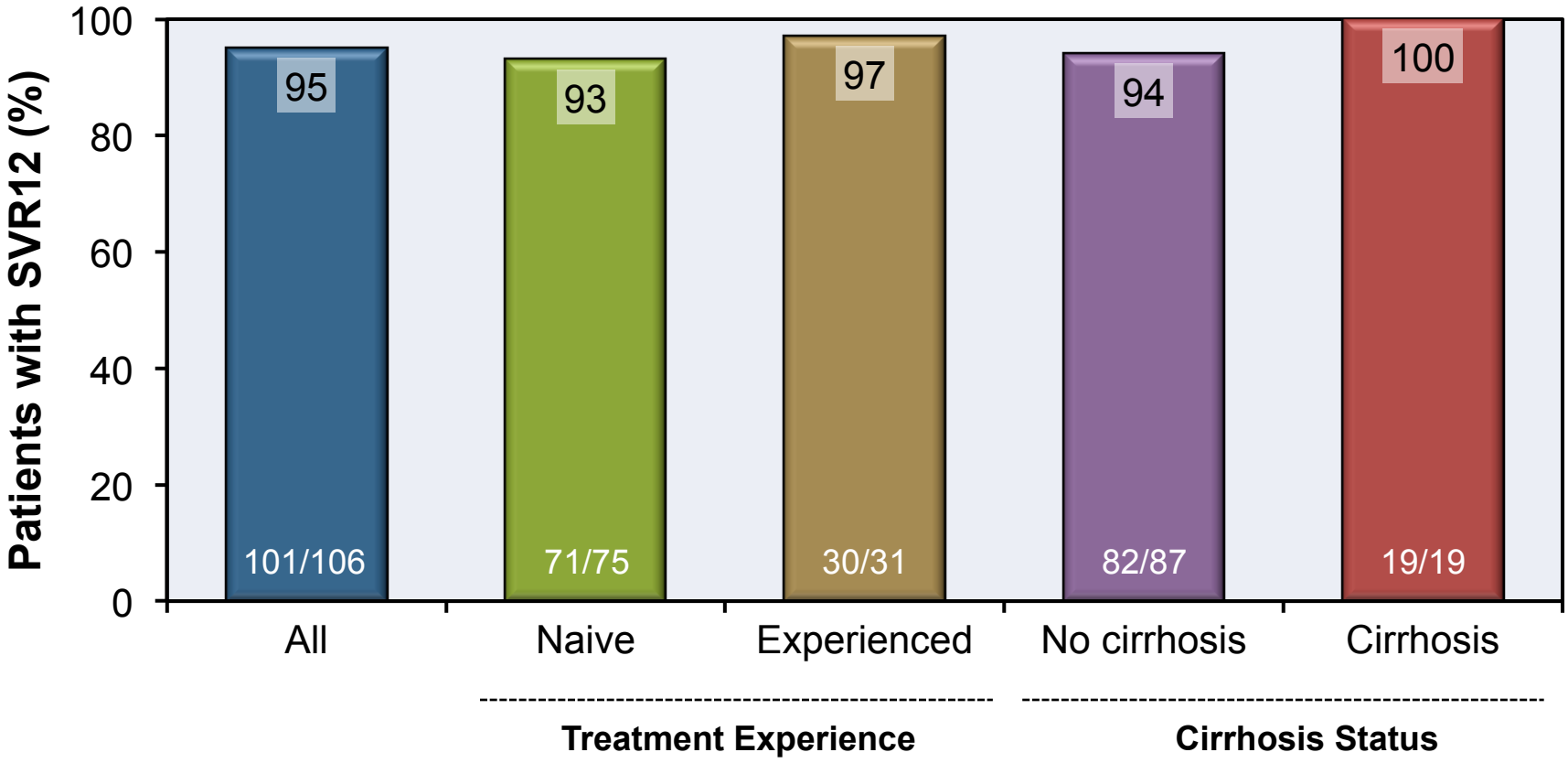
Hepatitis web study

Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients
ASTRAL-5: Results

ASTRAL-5: SVR12 Results by Cirrhosis & Treatment Experience



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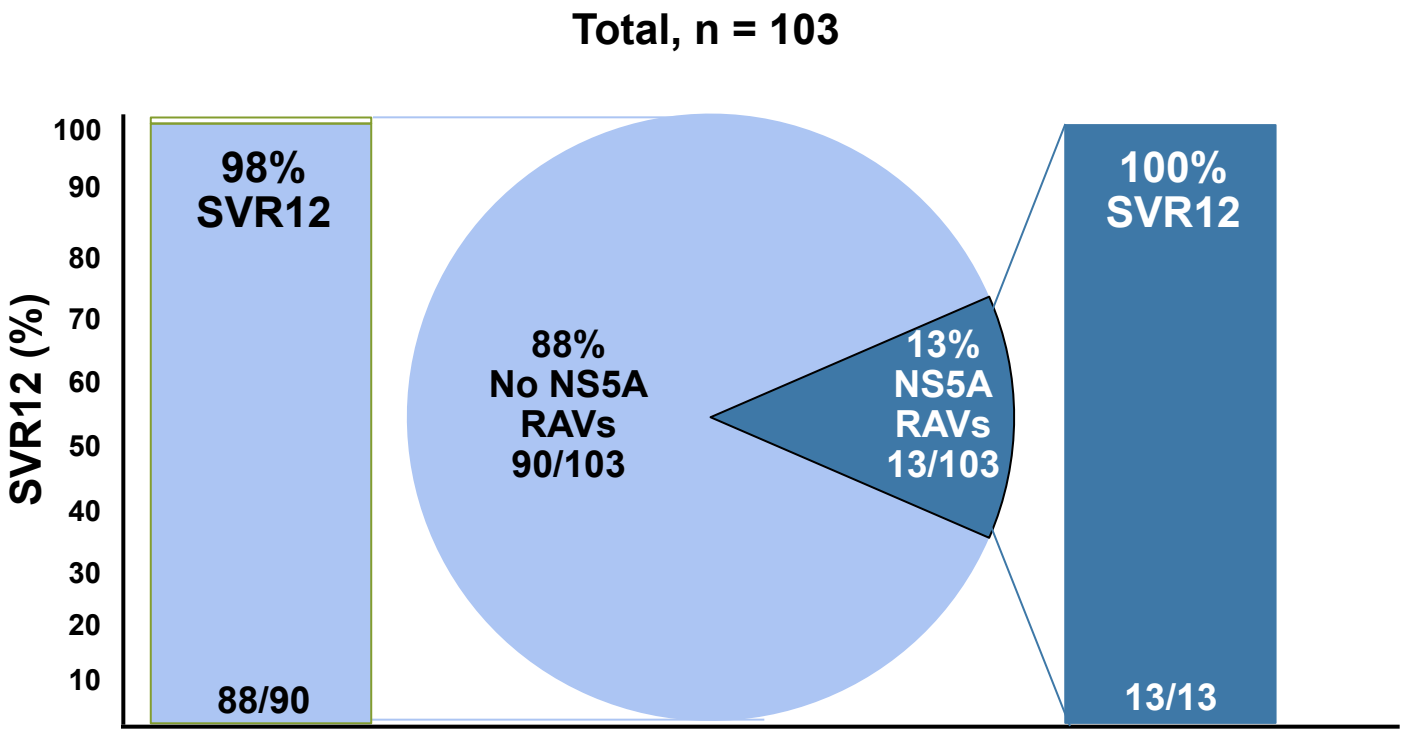
Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients
ASTRAL-5: Resistance

Baseline NS5A Resistance-Associated Variants and SVR12



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Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients
ASTRAL-5: Adverse Events

Adverse Event (AE), n (%)	Sofosbuvir-Velpatasvir (N=106)
Discontinuation due to AE	2 (2)
Serious AEs	2 (2)
Deaths	0
Any AE in >5% of patients	
Fatigue	26 (25)
Headache	14 (13)
Arthralgia	9 (8)
Upper respiratory tract infection	9 (8)
Diarrhea	9 (8)
Insomnia	7 (7)
Nausea	7 (7)

The majority of AEs were mild in severity (grade 1 or 2).
No patient with confirmed on-treatment HIV virologic breakthrough.

Source: Wyles D, et al. Clin Infect Dis. 2017 March 29. [Epub ahead of print]

Sofosbuvir-Velpatasvir in HIV-HCV Coinfected Patients
ASTRAL-5: Conclusions

Conclusions: “Sofosbuvir-velpatasvir for 12 weeks was safe and provided high rates of SVR12 in patients coinfected with HCV and HIV-1.”

Source: Wyles D, et al. Clin Infect Dis. 2017 March 29. [Epub ahead of print]