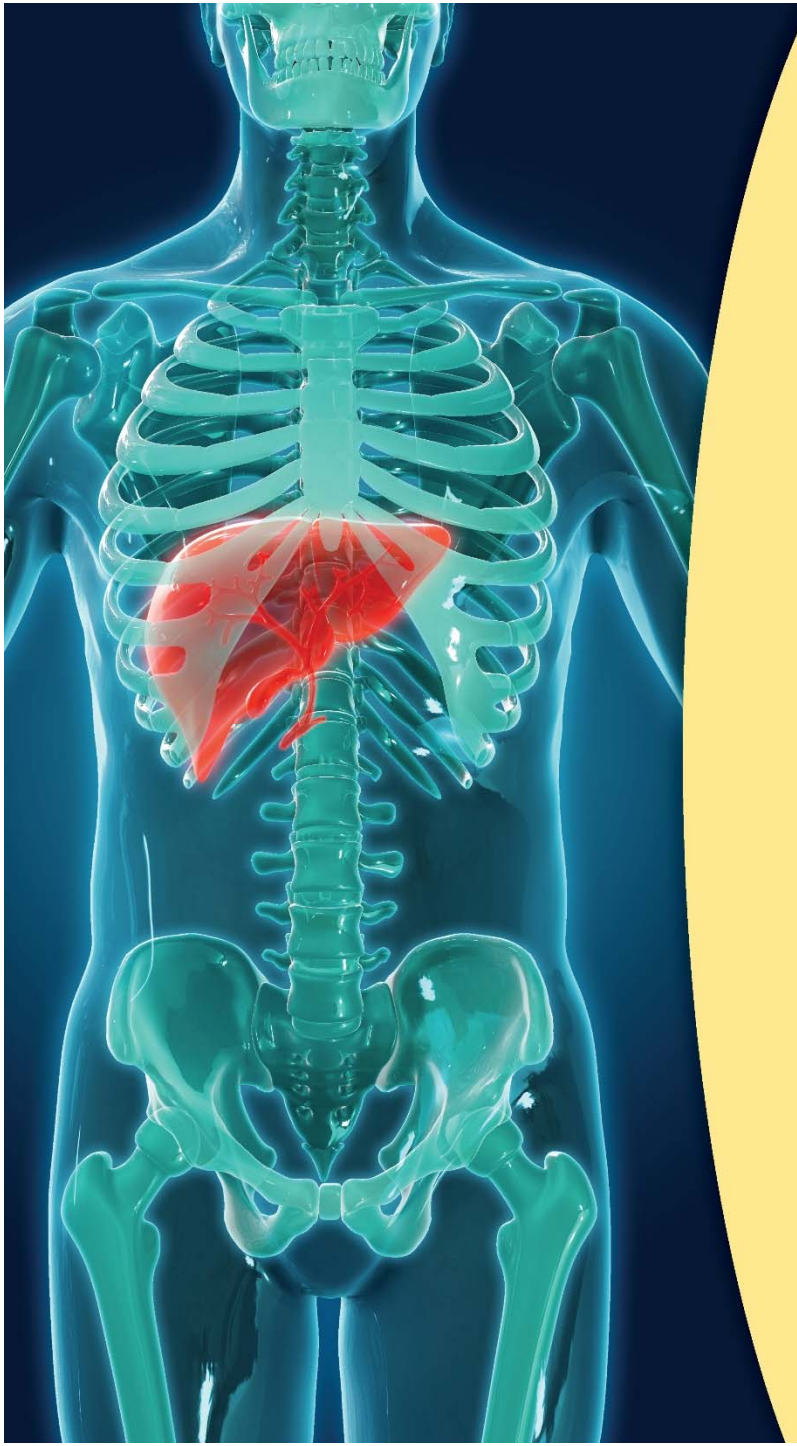

Complimentary CME/CE

Capacity Building in **Hepatitis C:**

Choosing and Optimizing Treatment

Presented by the AGA Institute and Med-IQ.

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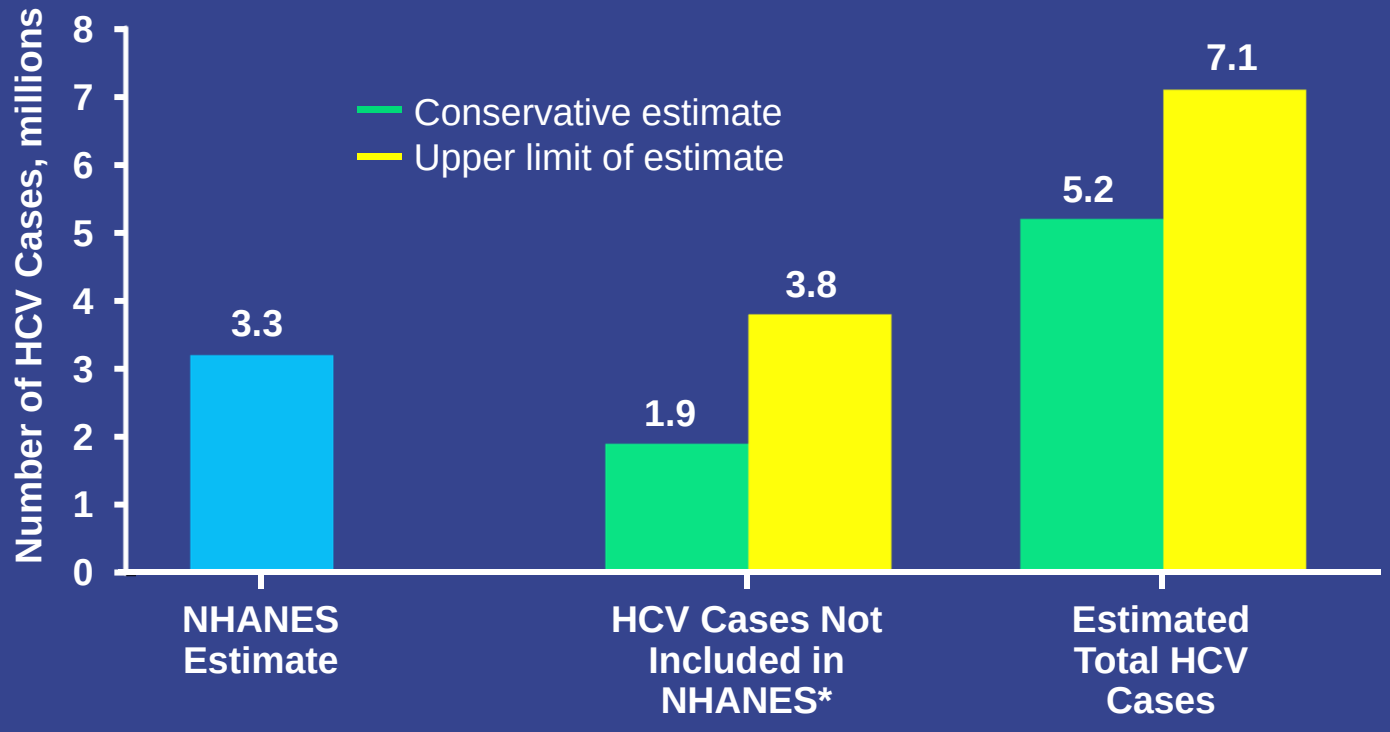
Learning Objectives

After completing this educational activity, participants should be able to:

- Discuss the benefits and limitations of novel direct-acting antiviral agents for the management of patients with chronic HCV infection
- Evaluate the impact of prior treatment when choosing direct-acting antiviral therapy for HCV management

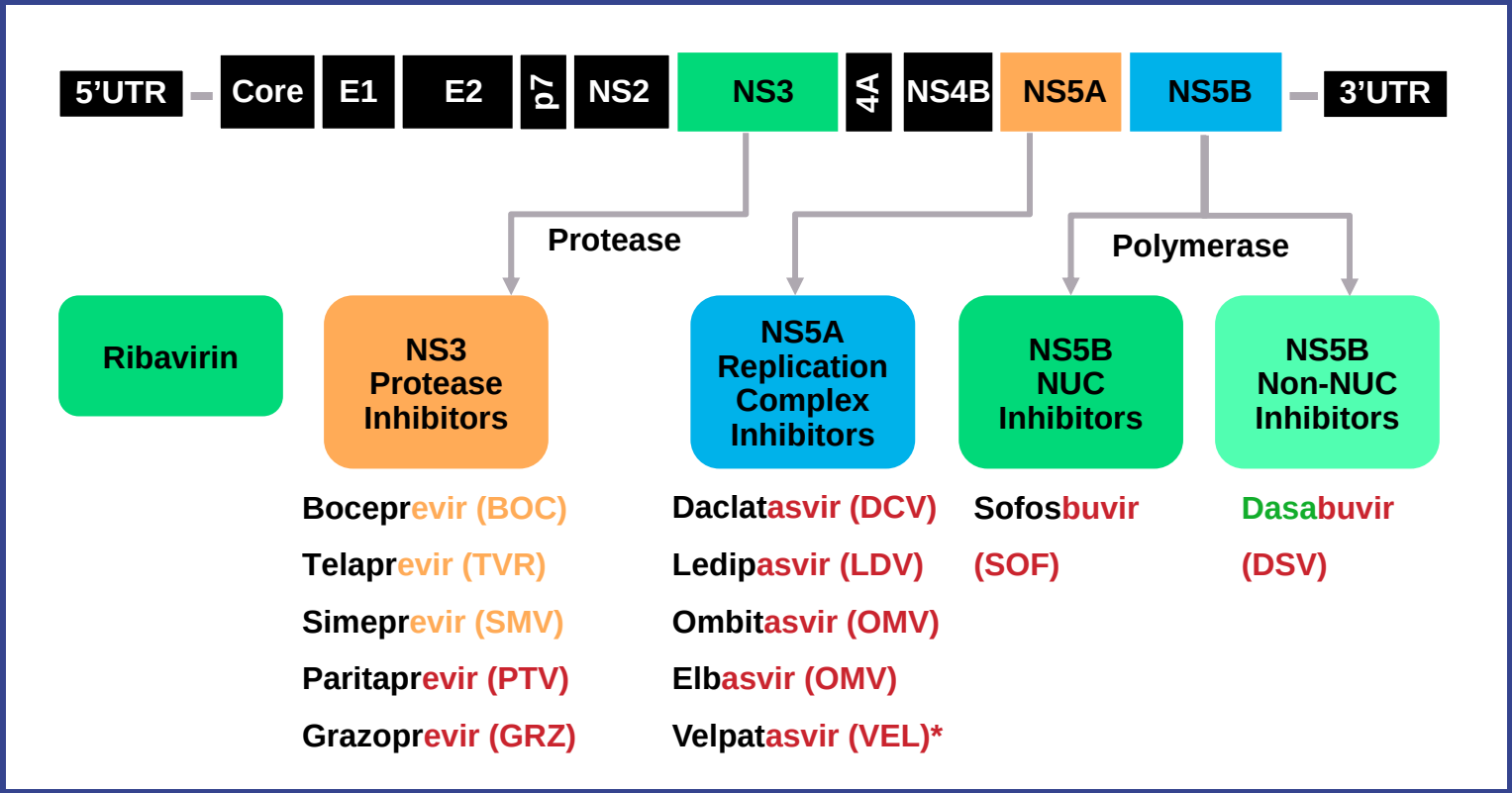
More Than 5.2 Million People With Chronic HCV in the US



Homeless (n = 142,761 to 337,6100); incarcerated (n = 372,754 to 664,826); veterans (n = 1,237,461 to 2,452,006); active military (n = 6,805); healthcare workers (n = 64,809 to 259,234); nursing home residents (n = 63,609); chronic hemodialysis (n = 20,578); hemophiliacs (n = 12,971 to 17,000).
*Original NHANES estimate minus HCV cases attributed to veterans (4,060,000 total - 790,000 veterans).

Chak E, et al. *Liver Int.* 2011;31:1090-101.

Approved DAAs From Multiple Classes

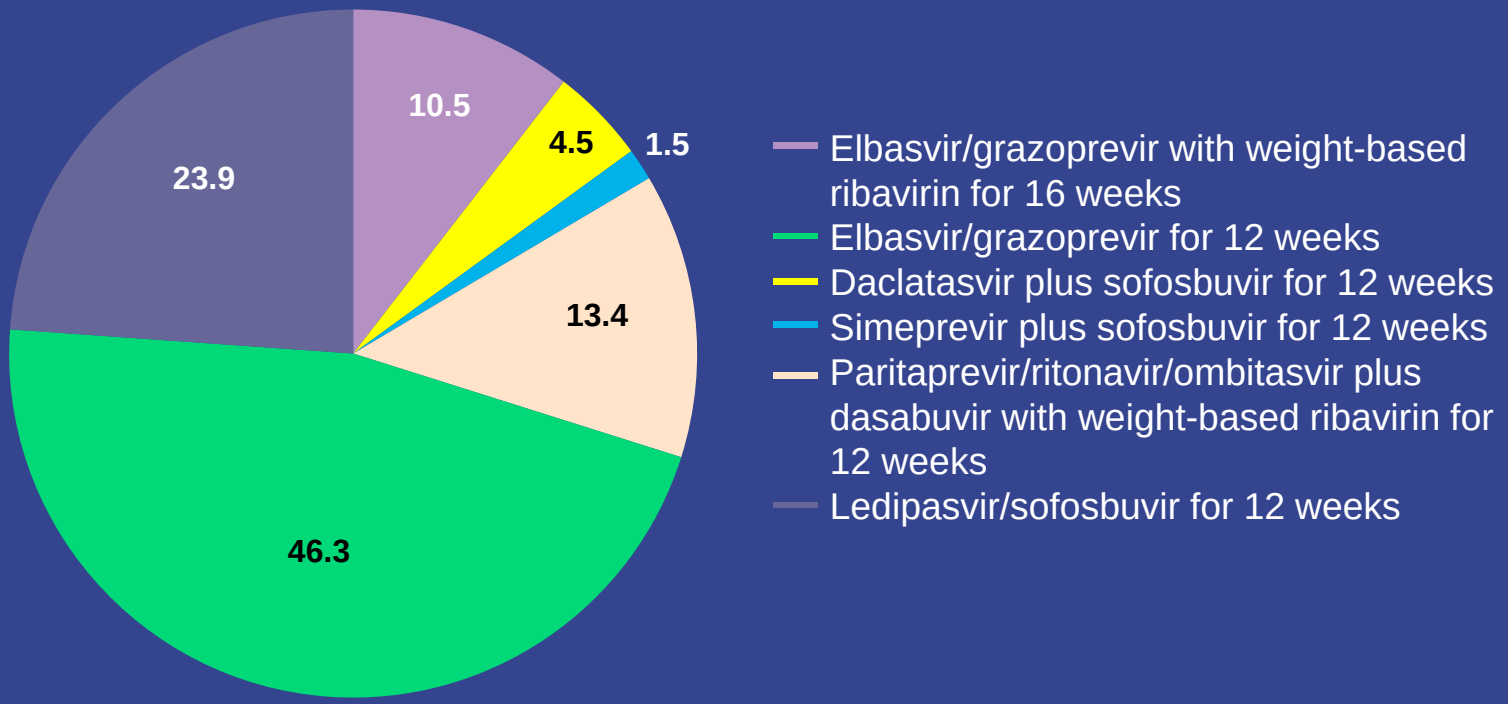


- Note the common root name for each drug class

*Investigational.

Derived from prescribing information for individual agents.

- RL is a 56-year-old woman who was recently diagnosed with HCV GT 1a with a viral load of 3,000,000 IU/mL. Initial examination shows that her liver chemistries are normal. Resistance testing demonstrates no detectable baseline NS5A RAVs for EBR. Which of the following regimens would you choose as initial therapy for RL?


10.5
4.5
1.5
13.4
46.3
23.9
Elbasvir/grazoprevir with weight-based ribavirin for 16 weeks
Elbasvir/grazoprevir for 12 weeks
Daclatasvir plus sofosbuvir for 12 weeks
Simeprevir plus sofosbuvir for 12 weeks
Paritaprevir/ritonavir/ombitasvir plus dasabuvir with weight-based ribavirin for 12 weeks
Ledipasvir/sofosbuvir for 12 weeks

HCV Genotype 1

Treatment-Naïve, Noncirrhotic Patients

NOT HEAD-TO-HEAD TRIALS

Regimen	Weeks	Study	SVR12
SOF + LDV (HCV RNA < 6 M IU/mL) (HCV RNA > 6 M IU/mL)	 8 12	ION-3	 119/123 (97%) 206/216 (95%)
EBR/GZR 1b and -NS5A RAVs (1a)	12	C-EDGE	133/135 (99%) 129/131 (99%)
PrOD (1b)	12	PEARL III	207/209 (99%)
PrOD +/- RBV (1a)	12	PEARL IV SAPPHIRE-I	97/100 (97%) 307/322 (95%)
SIM + SOF	12	COSMOS OPTIMIST-1	20/21 (95%) 112/115 (97%)
DCV + SOF	12	ALLY-2 (HIV coinfected)	70/72 (97%)

AEs included nausea, headache, and fatigue.

AASLD/IDSA/IAS–USA.
Recommendations for testing, managing, and treating hepatitis C.
www.hcvguidelines.org. Accessed 5/13/2016.

HCV Genotype 2

Population	Regimen	Weeks	Study	SVR12
Naïve				
No Cirrhosis	SOF + RBV	12	FISSION, POSITRION, VALENCE	201/214 (97%)
Cirrhosis	SOF + RBV	16	FUSION	7/9 (78%) TE
RBV Intolerant	DCV + SOF	12	ALLY-2 (HIV)	11/11 (100%)
Experienced (PEG-IFN/RBV)				
No Cirrhosis	SOF + RBV	16	FUSION	23/23 (100%)
Cirrhosis	SOF + RBV	24	BOSON	17/17 (100%)
Experienced (SOF/RBV)				
± Cirrhosis	DCV + SOF +/- RBV	24		
	PEG-IFN + RBV + SOF	12	BOSON	

AEs included nausea, headache, and fatigue.

AASLD/IDSA/IAS–USA.
Recommendations for testing, managing, and treating hepatitis C.
www.hcvguidelines.org. Accessed 5/13/2016.

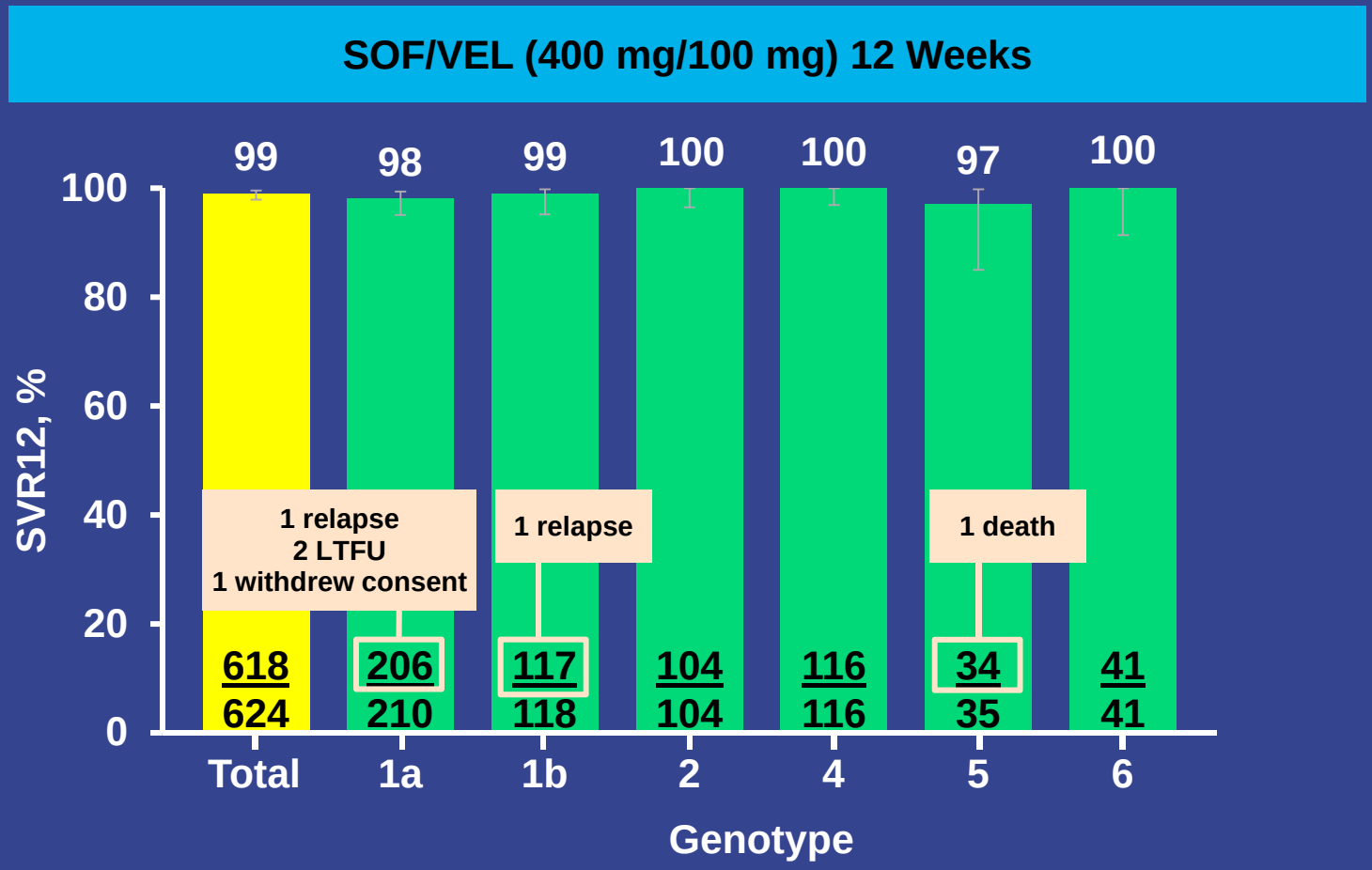
HCV Genotype 3

Population	Regimen	Weeks	Study	SVR12
Naive				
No Cirrhosis	DCV + SOF	12	ALLY-3	73/75 (97%)
Cirrhosis	DCV + SOF +/- RBV	24	EU Compassionate Use Program	~88%
Experienced (PEG-IFN/RBV)				
No Cirrhosis	DCV + SOF	12	ALLY-3 (-RBV)	32/34 (94%)
Cirrhosis	DCV + SOF + RBV	24	EU Compassionate Use Program	
Experienced (SOF/RBV)				
± Cirrhosis	DCV + SOF + RBV	24	EU Compassionate Use Program	
TN and TE ± Cirrhosis	PEG-IFN + RBV + SOF	12	BOSON	96% TN NC (71) 91% TN Cir (23) 94% TE NC (52) 86% TE Cir (35)

AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org. Accessed 5/13/2016.

AEs included nausea, headache, and fatigue.

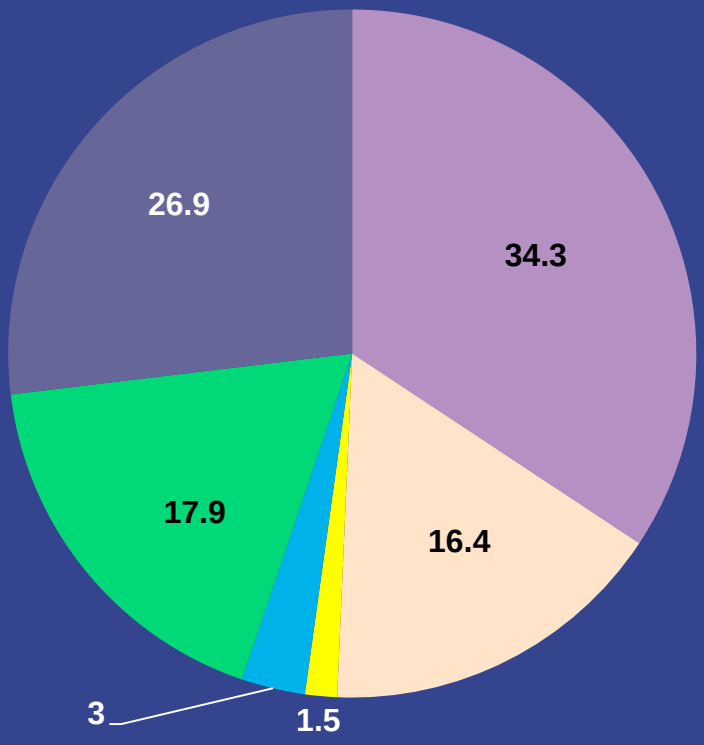
SOF/VEL SVR12 by GT: Entering the Era of the Class of “Perfectovirs”?



Error bars represent 95% confidence intervals.
AEs included headache, fatigue, nasopharyngitis, and nausea.

Feld JJ, et al. *N Engl J Med*. 2015;373:2599-607.

- ST is a 62-year-old man who was diagnosed with HCV GT 1b and METAVIR stage F1 fibrosis 4 years ago. He was initially treated with a course of PEG-IFN, RBV, and SOF. At a recent follow-up appointment, he had a detectable HCV RNA level. Which of the following regimens would you prescribe for ST at this point?



- None of the above; I would obtain NS5A and NS3 resistance testing, including testing for the Q80K polymorphism
- Elbasvir/grazoprevir for 12 weeks
- Daclatasvir plus sofosbuvir for 12 weeks
- Simeprevir plus sofosbuvir for 12 weeks
- Paritaprevir/ritonavir/ombitasvir plus dasabuvir with weight-based ribavirin for 12 weeks
- Ledipasvir/sofosbuvir for 12 weeks

HCV Genotype 1

Treatment-Experienced (PEG-IFN/RBV), Noncirrhotic Patients

NOT HEAD-TO-HEAD TRIALS

Regimen	Weeks	Study	SVR12
SOF + LDV (PEG-IFN/RBV or PI + PEG-IFN/RBV)	12	ION-2	83/87 (95%)
PrOD (1b)	12	PEARL II SAPPHIRE-II (+ RBV)	91/91 (100%) 119/123 (97%)
PrOD + RBV (1a)	12	SAPPHIRE-II	166/173 (96%)
SIM + SOF	12	COSMOS OPTIMIST-1	20/21 (95%) 38/40 (95%)
DCV + SOF	12	ALLY-2	28/28 (100%)
EBR + GZR 1b and 1a (RAV-)	12	C-Edge	190/192 (99%)

AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. www.hcvguidelines.org. Accessed 5/13/2016.

HCV Genotype 1

Treatment-Experienced, Cirrhotic Patients

NOT HEAD-TO-HEAD TRIALS

Regimen	Weeks	Study	SVR12
SOF + LDV (PEG-IFN/RBV or PI + PEG-IFN/RBV)	24 12 + RBV	ION-2 SOLAR-I	22/22 (100%) 74/77 (96%)
PrOD (1b)	12	TURQUOISE-III	33/33 (100%)
EBR + GZR 1b and 1a (RAV-)	12	C-EDGE	
SIM + SOF +/- RBV and ✓Q80K GT 1a	24	COSMOS OPTIMIST-2 (12 wk)	11/12 (92%) 42/53 (79%)
DCV + SOF +/- RBV	24	ALLY-2 (no RBV) (HIV Coinfected)	12/13 (92%)

Feld JJ, et al. *J Hepatol*. 2016;64:301-7;
Lawitz E, et al. *Lancet*. 2014;384:1756-65;
Lawitz E, et al. *Hepatology*. 2015.[epub ahead of print];
Kwo P, et al. EASL. April 22-26, 2015; Vienna, Austria;
Wyles DL, et al. *N Engl J Med*. 2015;373:714-25;
Charlton M, et al. *Gastroenterology*. 2015;149:649-59.

Acknowledgment of Commercial Support

This activity is supported by educational grants from AbbVie and Gilead Sciences, Inc.

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