Sofosbuvir-Velpatasvir-Voxilaprevir in DAA-Experienced GT 1
RESOLVE

Source: Wilson E, et al. J Hepatol. 2019;71:498-504.

Sofosbuvir-Velpatasvir-Voxilaprevir in DAA-Experienced GT 1 RESOLVE: Study Features

- **Design**: Open-label, phase 2b trial to evaluate the efficacy of a fixed-dose combination of sofosbuvir-velpatasvir-voxilaprevir for 12 weeks in adults with chronic HCV GT 1 infection and a history of virologic rebound following DAA therapy
- **Setting**: 3 sites in United States
- **Entry Criteria**
  - Age >18 years
  - Chronic HCV genotype 1
  - HCV RNA ≥1,000 IU/mL at screening
  - Prior treatment failure with DAA treatment of 8 or more weeks duration
  - Participants with HIV and/or compensated cirrhosis allowed
- **Primary End Point**: SVR12

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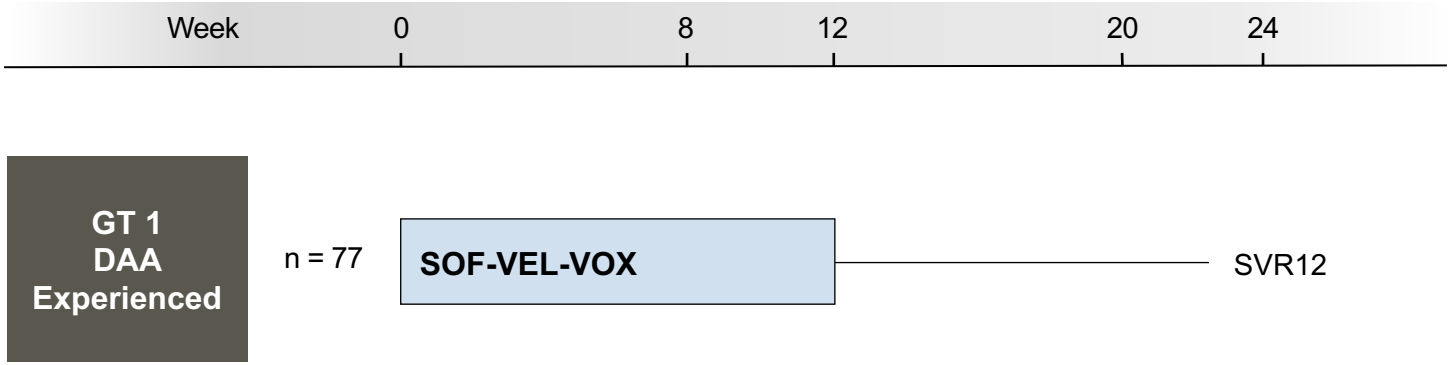
Sofosbuvir-Velpatasvir-Voxilaprevir in DAA-Experienced GT 1 RESOLVE: Study Design



Abbreviations: SOF, sofosbuvir; VEL, velpatasvir; VOX = voxilaprevir

Drug Dosing
SOF-VEL-VOX (400/100/100 mg): fixed dose combination; one pill once daily

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Sofosbuvir-Velpatasvir-Voxilaprevir in DAA-Experienced GT 1
RESOLVE: Baseline Characteristics

Baseline Characteristic	**SOF-VEL-VOX** x 12 weeks (n = 77)
Age, mean (± SD)	60 (± 8)
Male, n (%)	64 (83)
Black, n (%)	66 (86)
Hispanic, n (%)	0
HCV subtype, n (%) 1a 1b	 58 (75) 19 (25)
Fibrosis stage, n (%) F0-F2 F3 F4	 28 (36) 18 (23) 31 (40)
Coinfections, n (%) HIV HIV/HBV	 17 (22) 2 (3)
History of injection drug use	39 (51)

Abbreviations: SD, standard deviation, HBV, chronic hepatitis B

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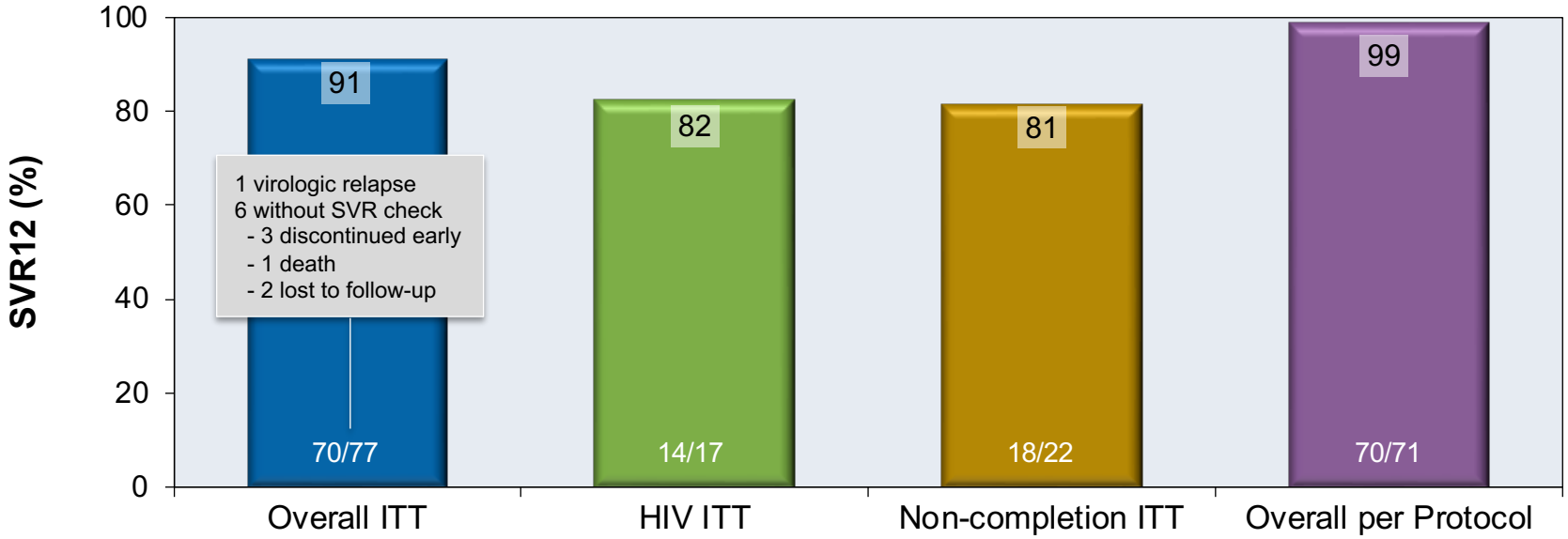
Sofosbuvir-Velpatasvir-Voxilaprevir in DAA-Experienced GT 1 RESOLVE: Baseline Characteristics

Baseline Characteristic	**SOF-VEL-VOX** x 12 weeks (n = 77)
Previous DAA regimen*, n (%)	
Ledipasvir-Sofosbuvir	69 (89)
Paritaprevir-Ombitasvir-ritonavir-Dasabuvir	3 (4)
Daclatasvir-Asunaprevir	3 (4)
Elbasvir-Grazoprevir	2 (3)
Simeprevir + Sofosbuvir	2 (3)
Daclatasvir + Sofosbuvir	1 (1)
Sofosbuvir-Velpatasvir	1 (1)
Prior interferon therapy, n (%)	13 (17)
Previous non-completion, n (%)	22 (29)
Poor adherence	14 (18)
Interruption	4 (5)
Lost or stolen medication	2 (3)
Adverse event	1 (1)

*Total number of regimens exceeds that of individual participants because some underwent >1 prior DAA regimens

Source: Wilson E, et al. J Hepatol. 2019;71:498-504.

Sofosbuvir-Velpatasvir-Voxilaprevir in DAA-Experienced GT 1 RESOLVE: Results



Abbreviations: ITT, intent-to-treat analysis.

Non-completion = Among those who had a history of prior non-completion. Per protocol, counting only those who completed 12 weeks of therapy

Source: Wilson E, et al. J Hepatol. 2019;71:498-504.

Sofosbuvir-Velpatasvir-Voxilaprevir in DAA-Experienced GT 1 RESOLVE: Conclusions

Conclusion: “In Retreatment with 12 weeks of sofosbuvir-velpatasvir-voxilaprevir was safe and effective in patients with relapsed HCV following initial combination DAA-based treatment. Treatment response was not affected by HIV coinfection or previous treatment course.”

Source: Wilson E, et al. J Hepatol. 2019;71:498-504.

Acknowledgments

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