Sofosbuvir-Velpatasvir in End-Stage Renal Disease on Dialysis

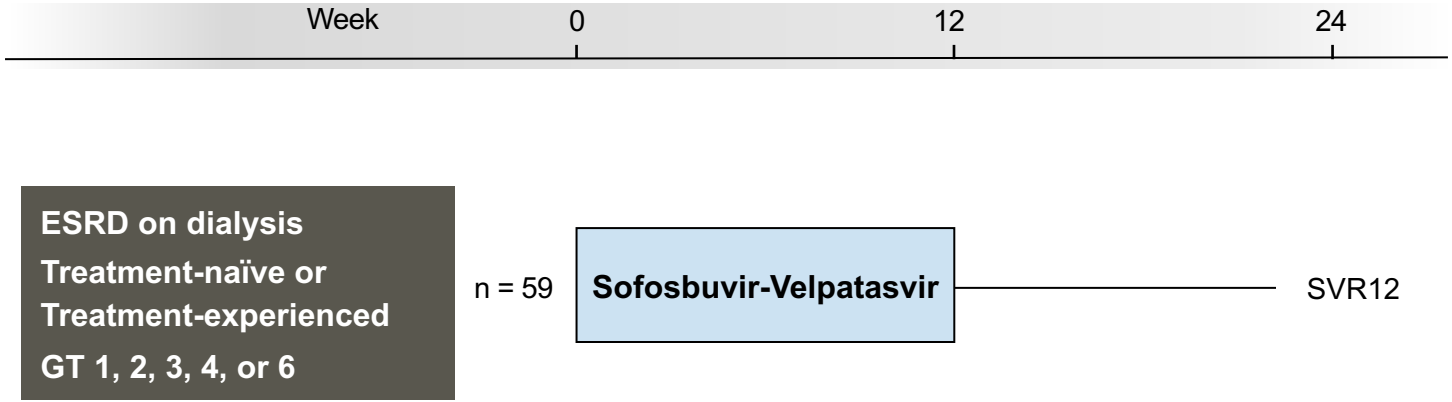
Source: Borgia SM, et al. J Hepatol. 2019;71:660-5.

Sofosbuvir-Velpatasvir in Patients with ESRD on Dialysis
Study Features

- **Design**: Single-arm, open-label, multicenter, phase 2 trial of sofosbuvir-velpatasvir for 12 weeks in end-stage renal disease patients on dialysis
- **Setting**: 22 sites in Canada, United Kingdom, Spain, Israel, New Zealand, and Australia
- **Entry Criteria**
  - Chronic HCV GT 1-6
  - Age ≥18 years
  - End-stage renal disease on peritoneal or hemodialysis
  - HIV coinfection allowed if stable on antiretroviral therapy x ≥8 weeks
  - Prior treatment failure allowed (but no prior NS5A or NS5B)
  - Patients with compensated cirrhosis allowed
- **Primary End Point**: SVR12

Source: Borgia SM, et al. J Hepatol. 2019;71:660-5.

Sofosbuvir-Velpatasvir in Patients with ESRD on Dialysis Study Design



Abbreviations: ESRD, end-stage renal disease

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

Source: Borgia SM, et al. J Hepatol. 2019;71:660-5.

Sofosbuvir-Velpatasvir in Patients with ESRD on Dialysis
Study Participants

Baseline Characteristic	Sofosbuvir-Velpatasvir (n = 59)
Age, mean, years (range)	60 (33-91)
Male, n (%)	35 (59)
Black race, n (%)	6 (10)
HCV genotype, n (%) 1a / 1b / other 2 3 4 6	 15 (25) / 11 (19) / 1 (2) 7 (12) 19 (32) 4 (7) 2 (3)
Body mass index, mean kg/m^2 (SD)	26 (17-39)
Mean HCV RNA, log_{10} IU/mL (range)	5.8 (3.1-7.7)
Cirrhosis, n (%)	17 (29)
Treatment experienced, n (%)	13 (22)

Source: Borgia SM, et al. J Hepatol. 2019;71:660-5.

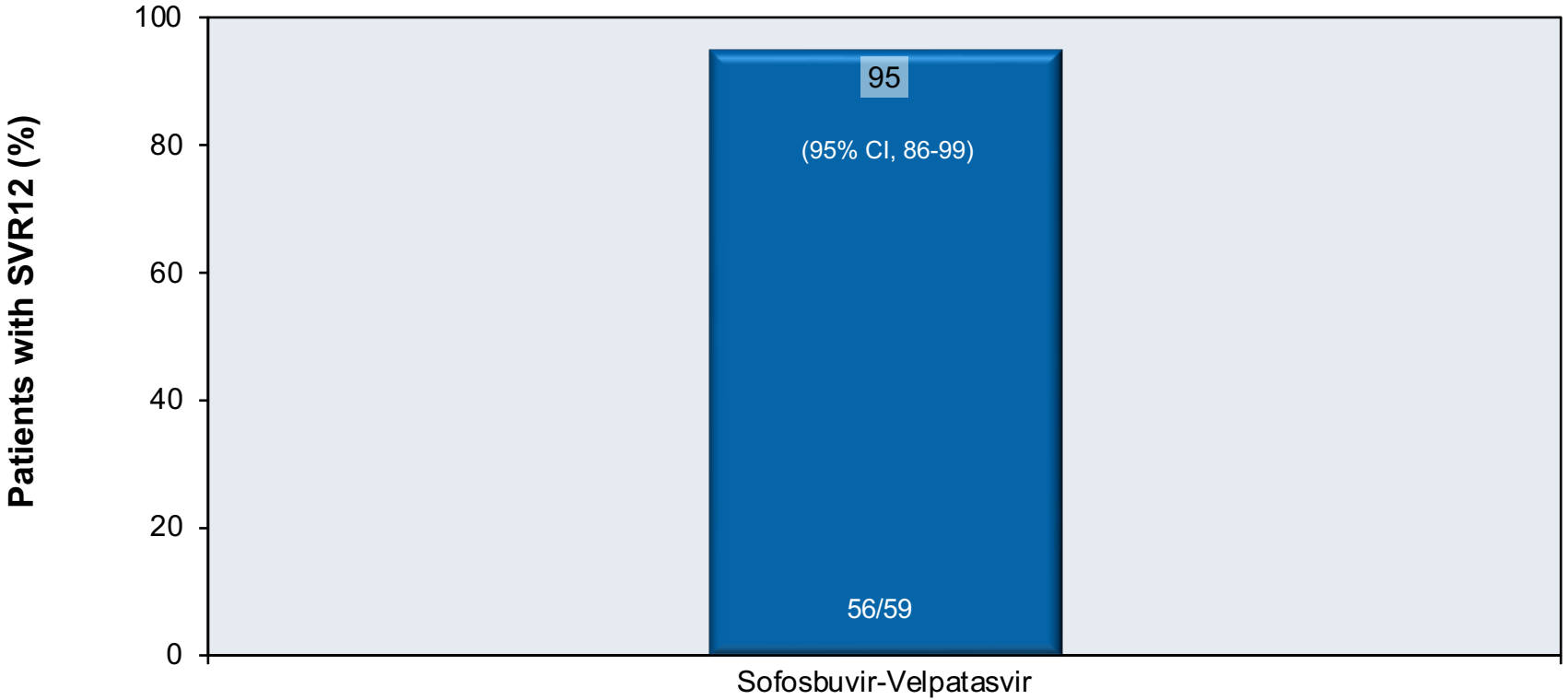
Sofosbuvir-Velpatasvir in Patients with ESRD on Dialysis
Study Participants

Other Characteristics	Sofosbuvir-Velpatasvir (n = 59)
Prior HCV treatment experience, n/N (%)	
Peg-IFN + ribavirin	6/13 (46)
Other	7 (13) (54)
Type of dialysis, n (%)	
Hemodialysis	54 (92)
Peritoneal dialysis	5 (9)
Mean duration of dialysis, years (range)	7 (0-40)
Prior renal transplant, n (%)	19 (32)

Abbreviations: Peg-IFN, pegylated interferon

Source: Borgia SM, et al. J Hepatol. 2019;71:660-5.

Sofosbuvir-Velpatasvir in Patients with ESRD on Dialysis Results: ITT Analysis



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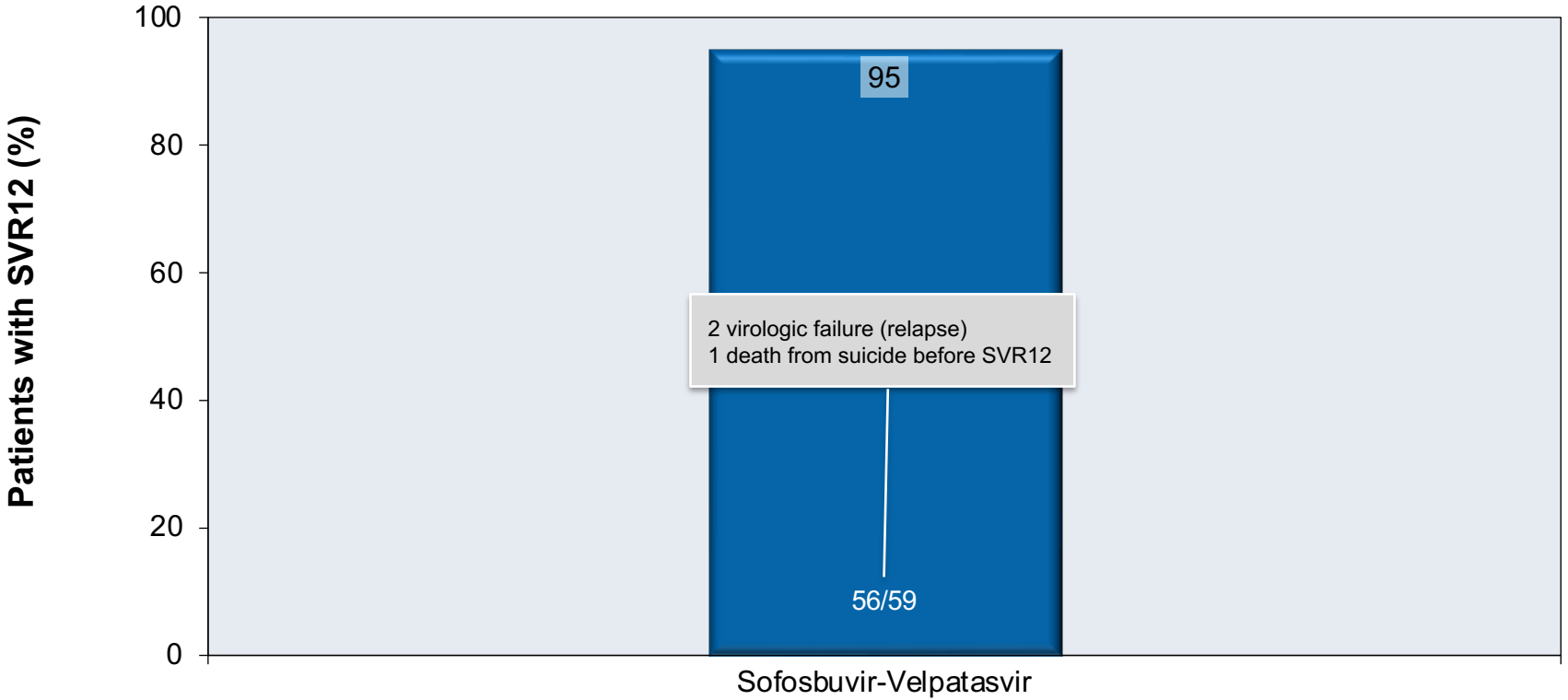
Sofosbuvir-Velpatasvir in Patients with ESRD on Dialysis Results: ITT Analysis



Source: Borgia SM, et al. J Hepatol. 2019;71:660-5.

Sofosbuvir-Velpatasvir in Patients with ESRD on Dialysis Results: Adverse Events

Adverse Events (AEs), n (%)	Sofosbuvir-Velpatasvir (n = 59)
Any adverse event	47 (80)
Grade 3 AEs	7 (12)
Serious AEs	11 (19)
AE leading to SOF-VEL discontinuation	0
Deaths	2 (3)
AEs occurring in ≥10% patients	
Headache	10 (17)
Fatigue	8 (14)
Nausea	8 (14)
Vomiting	8 (14)
Insomnia	6 (10)

Abbreviations: SOF-VEL, sofosbuvir-velpatasvir

Source: Borgia SM, et al. J Hepatol. 2019;71:660-5.

Sofosbuvir-Velpatasvir in Patients with ESRD on Dialysis Results: Laboratory Abnormalities

Grade 3-4 Lab Abnormalities, n (%)	Sofosbuvir-Velpatasvir (n = 59)
Creatinine	
Grade 3	1 (2)
Grade 4	14 (24)
Hyperglycemia	
Grade 3	5 (9)
Hemoglobin	
Grade 3	4 (7)
Hyperkalemia	
Grade 3	2 (3)
Grade 4	1 (2)

Source: Borgia SM, et al. J Hepatol. 2019;71:660-5.

Sofosbuvir-Velpatasvir in Patients with ESRD on Dialysis Conclusions

Conclusions: “Treatment with sofosbuvir/velpatasvir for 12 weeks was safe and effective in patients with ESRD undergoing dialysis.”

Source: Borgia SM, et al. J Hepatol. 2019;71:660-5.

Acknowledgments

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