



REPORTING ON EASL 2017
**ADVANCES IN CHRONIC HEPATITIS C:
MANAGEMENT AND TREATMENT**
**COMPREHENSIVE EXPERT REVIEW
AND DISCUSSION OF KEY PRESENTATIONS**

AN INDEPENDENT CME ACTIVITY JOINTLY PROVIDED BY POSTGRADUATE INSTITUTE FOR MEDICINE AND VIRALD, INC.
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Real World Effectiveness

Mark Sulkowski, MD
Professor of Medicine
Johns Hopkins University School of Medicine



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Real World Experience with Elbasvir/Grazoprevir in the Veterans Affairs Healthcare System

J.R. Kramer, A. Puenpatom, K. Erickson, Y. Cao, H. El-Serag, F. Kanwal

Abstract PS-095



Real World VA Study: Objective and Methods

Objective:

- To evaluate the real-world effectiveness of EBR/GZR regimens in HCV-infected patients in the U.S. Veterans Health Administration

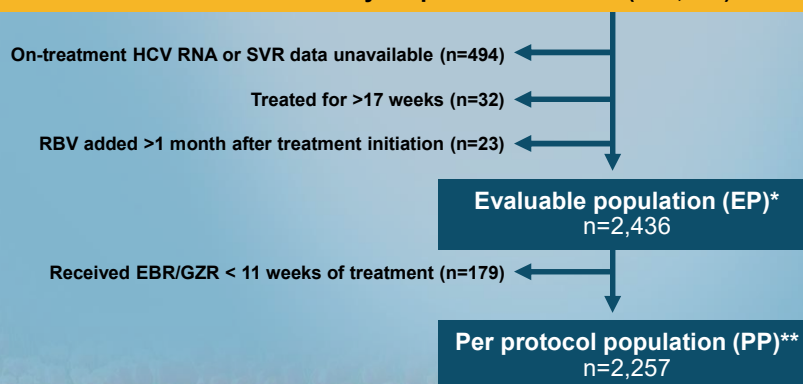
Methods:

- *Study design and data source:*
 - Retrospective database analysis using the VA Corporate Data Warehouse (CDW)
 - A national, repository of data from VA electronic medical records, since 1999
- *Study period:*
 - Treatment initiation period: February 1, 2016 to August 1, 2016
 - Follow up period: until February 15, 2017
- *Inclusion criteria:*
 - ≥18 years, positive HCV RNA
 - Had ≥1 prescription of EBR/GZR during treatment initiation period
 - ≥1 inpatient or outpatient visit within 1 year prior to treatment initiation
- *Exclusion criteria:*
 - Patients who were treated >17 weeks, or had RBV added >1 month after treatment initiation

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Real World VA Study: Study Population

HCV-infected Patients initiated EBR/GZR from Feb 1-Aug 1, 2016,
≥ 18 years, positive HCV RNA, ≥1 inpatient or outpatient visit within
1 year prior to treatment (n=2,985)



* Per Protocol (PP) denominator limited to patients who completed treatment course
** Evaluable population (EP) denominator – all patients with SVR outcomes available

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Real World VA Study: Definitions

- **SVR**

- HCV RNA below the limit of quantification performed at least 12 weeks after the end of treatment (SVR12)
- If HCV RNA data ≥ 12 weeks were not available, SVR was defined based on HCV RNA test available from week 4 to 12 weeks after the end of treatment*
 - 81% of the patients had SVR12 data

- **Analysis populations**

1. **Evaluable population (EP) SVR:** All patients who had HCV RNA test available at 4 weeks or more post treatment including patients who received EBR/GZR <11 weeks of treatment
2. **Per Protocol (PP) SVR:** Patients who completed treatment course and had virologic outcomes at 4 weeks or more post treatment

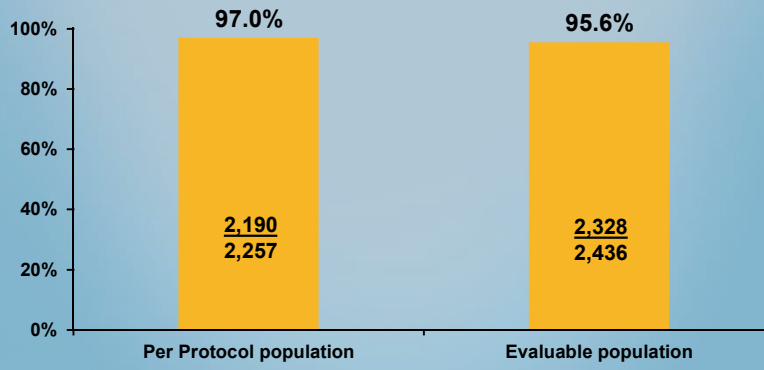
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Real World VA Study: Patient Characteristics (EP)

Characteristics	EBR/GZR Regimens N = 2,436	Characteristics	EBR/GZR Regimens N = 2,436
Age, mean (S.D)	63.5 (5.9)	Comorbidities, n (%)	
Male, n (%)	2350 (96.5)	Cirrhosis	808 (33.2)
Race/ethnicity, n (%)		CKD (stage 3-5)	800 (32.8)
African American	1400 (57.5)	Depression	1394 (57.2)
White	824 (33.8)	Diabetes	1295 (53.2)
Hispanic	81 (3.3)	History of drug abuse [†]	1313 (53.9)
Other	35 (1.4)	History of alcohol abuse [†]	1473 (60.5)
Genotype, n (%)		HIV	74 (3.0)
GT1 (all)**	2324 (95.4)	Prior Treatment, n (%)	
GT1a	844 (36.3)	Treatment naïve	1988 (81.6)
GT1b	1428 (61.5)	Previous treatment	
GT2, GT3	6 (0.3)	Prior PEG+/- RBV	316 (13.0)
GT4	64 (2.6)	Prior BOC/TEL	6 (0.3)
BVL >800,000 IU/ml, n (%)*	1560 (67.9)	Prior SOF/SIM+SOF	9 (0.4)
		Prior LDV/SOF	82 (3.4)
		Prior PrOD	35 (1.4)

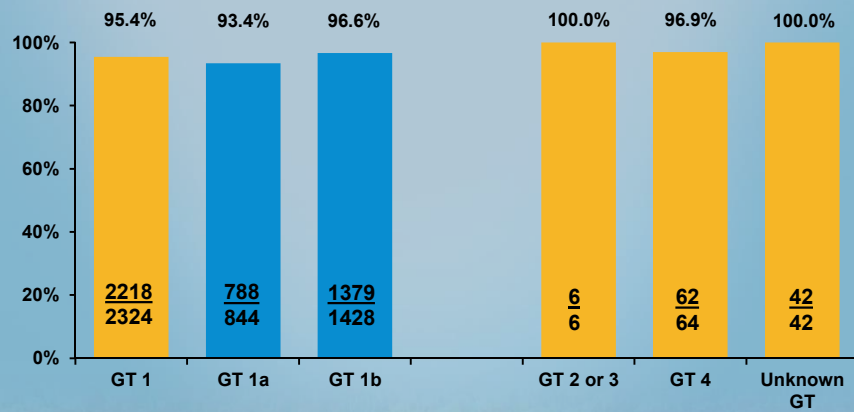
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Real World VA Study: Results - Overall SRV



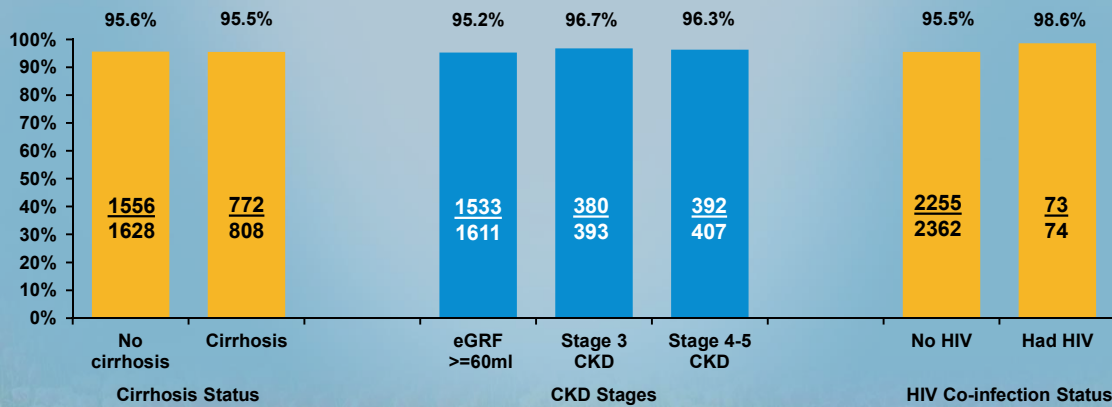
Kramer J, et al. 52nd EASL, Amsterdam, Netherlands; April 19-23, 2017. Abst. PS-095.

Real World VA Study: Results - SVR (EP) by Baseline Characteristics



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Real World VA Study: SVR (EP) in Cirrhosis, CKD, and HIV Subgroups



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Real World VA Study: Conclusions

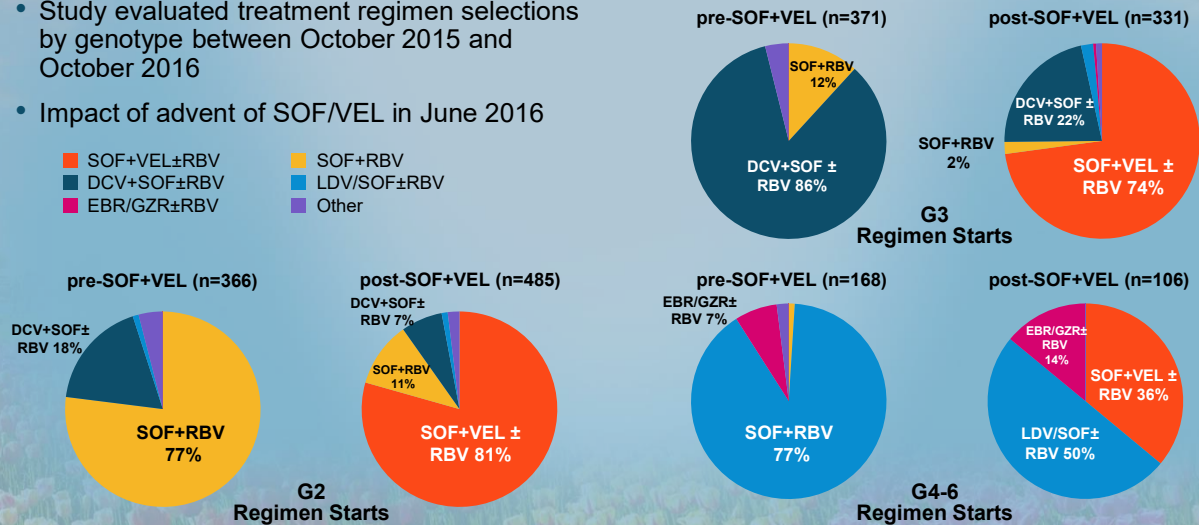
- Largest study of real world effectiveness of EBR/GZR to date
- EBR/GZR was highly effective, with an SVR of 95.6% overall (EP) and 97.0% in patients who completed a full course of treatment (PP)
- SVR rates were high across patient subgroups regardless of gender, race/ethnicity, presence of cirrhosis, renal impairment or HIV co-infection
- Real world effectiveness of EBR/GZR in the VA population is comparable to efficacy rates reported in clinical trials

Kramer J, et al. 52nd EASL, Amsterdam, Netherlands, April 19-23, 2017. Abst. PS-095.

Utilization of SOF/VEL in G2-6 HCV: Real-World Experience from the TRIO Network

- Study evaluated treatment regimen selections by genotype between October 2015 and October 2016
- Impact of advent of SOF/VEL in June 2016

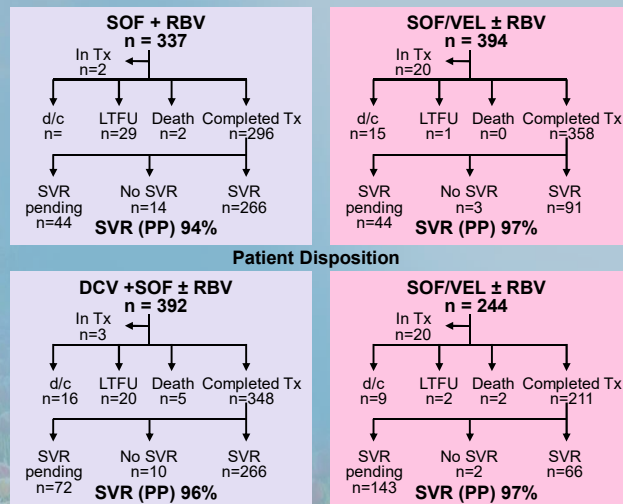
- SOF+VEL±RBV
- DCV+SOF±RBV
- EBR/GZR±RBV
- SOF+RBV
- LDV/SOF±RBV
- Other



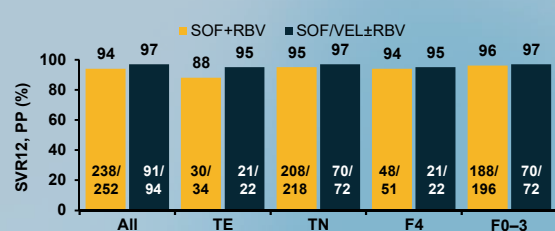
Curry M, et al. 52nd EASL: Amsterdam, Netherlands, April 19-23, 2017. Abst. PS-102.

TRIO Study: Patient Disposition and SVR12 (GT2-3)

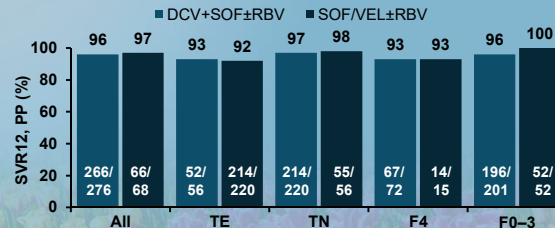
Patient Disposition



Genotype 2



Genotype 3



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TRIO Study: Patient Disposition (GT4-6)

GT4-6 Patient Disposition

