Effectiveness of the salvage therapy sofosbuvir/velpatasvir/voxilaprevir (SOF/VEL/VOX) in chronic hepatitis C; clinical practice experience from the TRIO network

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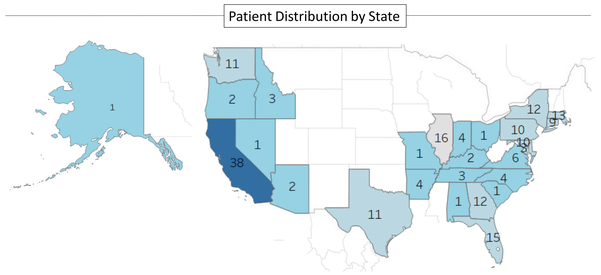
1. BACKGROUND AND AIMS

Although direct-acting antivirals (DAAs) failure is rare in clinical practice, SOF/VEL/VOX for 12-weeks is an FDA approved salvage therapy for patients that previously failed an NS5A inhibitor for any genotype or sofosbuvir without an NS5A inhibitor for GT1A or GT3. We report real-world data from the TRIO network on the utilization and efficacy of SOF/VEL/VOX in US patients.

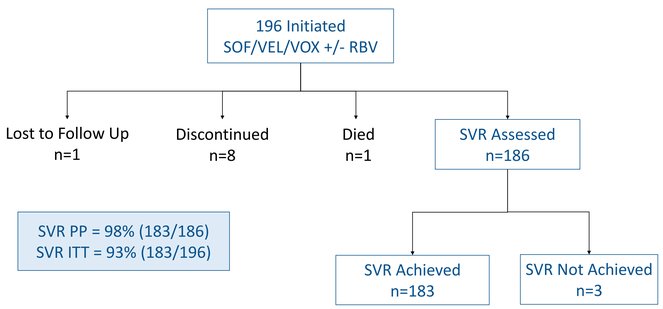
2. METHODS

Data from 196 patients who initiated SOF/VEL/VOX treatment between July 2017 to April 2018 were collected from providers and specialty pharmacies* through Trio Health's disease management program. The primary outcome assessed was Per Protocol (PP) sustained virologic response at 12 weeks post treatment (SVR12). Comparisons were conducted using chi-squared (categorical variables) or Student t test (continuous variables). Limitations are as follows. Reasons for discontinuations are not captured sufficiently to identify cause. Cause and timing of death are not available. Testing for resistance associated substitutions (RAS) is not commonly done and for this study sample, none of the patients had RAS details.



*Specialty Pharmacy Partners include Premier, Quality, AllCare, TFP Wellness Systems, Grubbs NW Specialty Pharmacy, and Value Specialty Pharmacy, LLC

3. PATIENT DISPOSITION



4. PATIENT CHARACTERISTICS

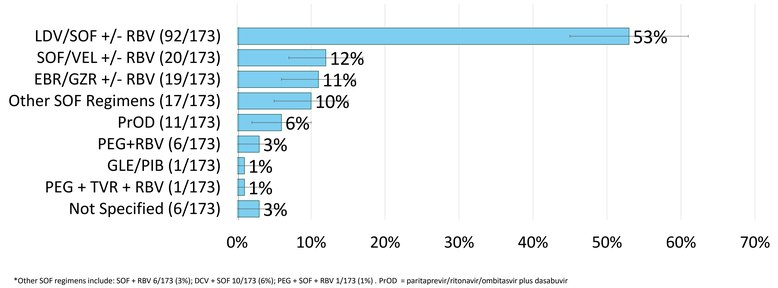
The majority of patients were treatment experienced (88%, 173/196) while only 11% (21/196) were treatment naïve. Almost half (42%, 82/196) were cirrhotic and 41% (81/196) had hypertension. 43% (77/179) of patients had a CKD Stage of 1-3 and more than half of the patients (60%, 117/194) had GT1A.

Metric – no. (%) unless indicated	Study Population* (n=196)	Subset: Treatment Experienced (n=173)	Subset: Treatment Naïve (n=21)	Subset: SOF/VEL/VOX + RBV Only (n=7)
+ RBV	7/196 (4%)	5/173 (3%)	2/21 (10%)	7/7 (100%)
Academic Practice Type	47/195 (24%)	42/173 (24%)	5/21 (24%)	2/7 (29%)
Payer Type				
Commercial	63/195 (32%)	59/173 (34%)	3/21 (14%)	2/7 (29%)
Medicaid	24/195 (12%)	24/173 (14%)	--	--
Medicare	105/195 (54%)	87/173 (50%)	18/21 (86%)	4/7 (57%)
Male	144/196 (73%)	131/173 (76%)	12/21 (57%)	5/7 (71%)
Age – mean (range)	61 (26-82)	60 (26-85)	63 (40-83)	62 (55-71)
Ethnicity				
Asian	5/196 (3%)	5/173 (3%)	--	--
Black	31/196 (16%)	26/173 (15%)	4/21 (19%)	--
Hispanic or Latino	12/196 (6%)	10/173 (6%)	2/21 (10%)	--
White	55/196 (28%)	53/173 (31%)	2/21 (10%)	2/7 (29%)
Other or Unspecified	93/196 (47%)	79/173 (46%)	13/21 (62%)	5/7 (71%)
Disease Severity				
FIB-4 <1.45	38/177 (21%)	35/159 (22%)	3/16 (19%)	--
FIB-4 1.45 to 3.25	68/177 (38%)	60/159 (38%)	6/16 (38%)	4/7 (57%)
FIB-4 >3.25	71/177 (40%)	64/159 (40%)	7/16 (44%)	3/7 (43%)
Cirrhosis[1]	82/196 (42%)	75/173 (43%)	6/21 (29%)	2/7 (29%)
No CKD Stage	100/179 (56%)	88/158 (56%)	12/20 (60%)	4/7 (57%)
CKD Stage 1-3	77/179 (43%)	68/158 (43%)	8/20 (40%)	3/7 (43%)
CKD Stage 4	2/179 (1%)	2/158 (1%)	--	--
Comorbidities				
Diabetes	41/196 (21%)	37/173 (21%)	4/21 (19%)	3/7 (43%)
Hypertension	81/196 (41%)	69/173 (40%)	11/21 (52%)	5/7 (71%)
Hyperlipidemia	22/196 (11%)	21/173 (12%)	1/21 (5%)	3/7 (43%)
Virology				
HIV Co-Infected	6/196 (3%)	4/173 (2%)	1/21 (5%)	--
Baseline VL >6MM IU/ml	32/193 (17%)	24/172 (14%)	7/19 (37%)	3/7 (43%)
GT1A	117/194 (60%)	102/171 (60%)	14/21 (67%)	2/7 (29%)
GT1B	30/194 (15%)	29/171 (17%)	1/21 (5%)	2/7 (29%)
GT1 (subtype mixed or unknown)	4/194 (2%)	--	3/21 (14%)	--
GT2	5/194 (3%)	4/171 (2%)	1/21 (5%)	--
GT3	32/194 (16%)	30/171 (18%)	2/21 (10%)	3/7 (43%)
GT4-6[2]	6/194 (3%)	6/171 (4%)	--	--
Treatment Experienced	173/194 (89%)	173/173 (100%)	--	5/7 (71%)

[1]fibrosis as reported by the physician, compensated/decompensated not known; [2]No patients had GT5
*2 patients did not have known prior treatment status

5. REGIMENS PRIOR TO SOF/VEL/VOX

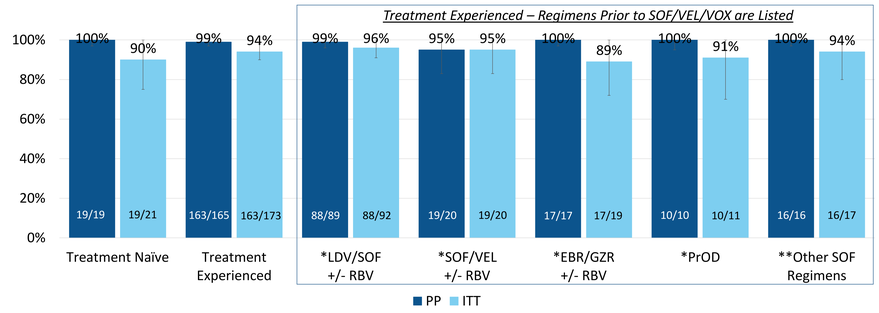
More than half the patients (53%, 92/173) previously received LDV/SOF +/- RBV with smaller numbers receiving SOF/VEL +/- RBV (12%, 20/173), EBR/GZR +/- RBV (11%, 19/173) and other SOF-based regimens (10%, 17/173).



*Other SOF regimens include: SOF + RBV 6/173 (3%); DCV + SOF 10/173 (6%); PEG + SOF + RBV 1/173 (1%) . PrOD = paritaprevir/ritonavir/ombitasvir plus dasabuvir

6. SVR RATES FOR SOF/VEL/VOX SUBGROUPS

ITT and PP rates were similar between treatment naïve and treatment experienced patients and did not significantly vary by prior regimen type.



*Prior Regimens. **Other SOF Regimens include: SOF + RBV; DCV + SOF; PEG + SOF + RBV. ***1 patient who previously received GLE/PIB achieved SVR12

7. SOF/VEL/VOX VIROLOGIC FAILURES

Virologic Failures	Patient	Baseline VL	Genotype	Fibrosis Score	Comorbids	Prior Regimen	Insurance
SVR Not Achieved	57, M, White	826,651	GT1A	4 – Cirrhosis	Hypertension	SOF/VEL	Commercial
SVR Not Achieved	71, M, White	13,051,000	GT1A	4 – Cirrhosis	HLD, HTN, CKD Stage 2	LDV/SOF + RBV	Medicare
SVR Not Achieved	69, F, Black	11,218,601	GT1	2 - Moderate	Depression, HTN, CKD Stage 2	Not Specified	Not Reported

HTN=Hypertension; HLD=Hyperlipidemia; CKD=Chronic Kidney Disease

8. SOF/VEL/VOX DISCONTINUATIONS

Discontinued rate was 4% (8/196). Of these patients, 2 were treatment naïve and 6 were treatment experienced (Prior Regimens include: 1 (SOF+RBV), 1 (PEG+RBV), 1 (EBR/GZR), 1 (PrOD), and 2 (LDV/SOF). The majority of discontinued patients had GT1 (6) while 1 was GT3 and 1 was Mixed. There were 5 discontinued patients that had a fibrosis score of F0-2, 2 patients that were cirrhotic (F4) and 1 that was no cirrhosis, score unknown. All discontinued patients were Medicare.

9. SUMMARY

Although DAA failure is rare in clinical practice, SOF/VEL/VOX is an FDA approved salvage therapy for patients that previously failed an NS5A inhibitor for any genotype or sofosbuvir without an NS5A inhibitor for GT1A or 3. Data from 196 patients who initiated SOF/VEL/VOX treatment between July 2017 to April 2018 were analyzed.

Majority (88%, 173/196) of patients were treatment experienced, while only 11% (21/196) were treatment naïve. More than half the patients (53%, 92/173) previously received LDV/SOF +/- RBV.

In clinical practice, ITT and PP rates were similar between treatment naïve and treatment experienced patients and did not significantly vary by prior regimen type. SOF/VEL/VOX SVR12 PP rates were 98% (183/186) and ITT rates were 93% (183/196).

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