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 NSSA 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.

3. PATIENT DISPOSITION

Lost to Follow Up n=1
Discontinued n=8
 Died n=1
SOF/VEL/VOX +/- RBV n=186

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% (77/173) of patients had a CDC Stage 1-3 and more than half of the patients (60%, 117/194) had GT1A.

5. REGIMENS PRIOR TO SOF/VEL/VOX

More than half the patients (53%, 192/373) 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 (29%, 17/173).

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.

7. SOF/VEL/VOX VIROLOGIC FAILURES

8. SOF/VEL/VOX DISCONTINUATIONS

Discontinued rates 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 (PRD), 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 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 NSSA inhibitor for any genotype or sofosbuvir without an NSSA inhibitor for GT1A or GT3. 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.

*Specialty Pharmacy Partners include Premier Quality, QualityCare, CVS Caremark, Inova, Value Specialty Pharmacy, and Value Specialty Pharmacy L L C.