DRUG USE AND REINFECTION DURING AND FOLLOWING HEPATITIS C VIRUS (HCV) TREATMENT WITH ELBASVIR/GRAZOPREVIR (EBR/GZR) AMONG PATIENTS RECEIVING OPIOID AGONIST THERAPY (OAT): THE C-EDGE CO-STAR STUDY

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Background:
High efficacy was observed in C-EDGE CO-STAR Part A, a phase 3 trial of EBR/GZR for 12 weeks in participants on OAT. CO-STAR Part B is the ongoing 3-year observational study of participants who received ≥1 dose of EBR/GZR in Part A (n=296). We provide analyses of urine drug screen (UDS) results, reported drug use, and a summary of reinfection in Part B.

Methods:
UDS (amphetamines, barbiturates, benzodiazepines, buprenorphine, cannabinoids, cocaine, methadone, opiates, phencyclidine, or propoxyphene) was performed at each visit in Parts A and B; additionally in Part B, patient-reported surveys were administered at each 6-month visit to assess risk behavior. If HCV RNA is detected at any visit, viral genotype and sequencing are assessed.

Results:
Drug use has remained constant in participants enrolled in Part B (n=199). Percentage of participants with a positive UDS (excludes cannabinoids, methadone, buprenorphine) remained relatively constant, with 48%, 48%, 54%, 49%, 46%, 47%, 39%, 36%, and 43% positive at day 1, treatment week (TW)12, follow-up week (FW)12, FW24, and months 6, 12, 18, 24, and 30, respectively. Similarly, reported drug use within the last month prior to each visit was comparable, with any-drug use reported by 50%, 47%, 48%, 45%, and 44%, at months 6, 12, 18, 24, and 30, respectively. HCV viral recurrence consistent with reinfection occurred in 6/296 participants through FW24, with a rate of 3.4 reinfections/100 person-years (95% confidence interval, 1.3–7.5); an additional 5 viral recurrences were identified in Part B (enrollment, months 6, 18, 24, 30).

Conclusion:
Drug use as assessed by UDS and patient report has remained comparable from the start of treatment throughout the ongoing 3-year follow-up period. HCV reinfection among patients on OAT following EBR/GZR therapy is uncommon, despite ongoing drug use. Additional follow-up data including specific risk behaviors will be reported.

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