Patients and Methods

Study Design: Part A

- C-EDGE was a phase 3, randomized, double-blind trial designed to evaluate EBR/GZR for 12 weeks in patients with HCV GT1, 4, or 6 infection on prior antiviral therapy (OAT) (Figure 2).

- Patients were on OAT for at least 3 months, and consistently kept at least 80% of scheduled appointments while on OAT.

- Patients on OAT at the day of active treatment, n (%): Amphetamines 31 (16), 6 (6); Benzodiazepines 43 (22), 34 (35); Opiates 42 (21), 21 (22); Alcohol 159 (80), 75 (77); Any one positive urine drug screen result 30 (15), 15 (15); African American 11 (6), 5 (5); Age, years, median (range) 48.6 (24-66), 44.1 (23-64).

- Urine drug screen results are shown in Table 2.

- Follow-up was conducted at 6 months and 12 months, with a median follow-up time of 12 months.

- SVR12: Sustained virologic response at 12 weeks.

- SVR24: Sustained virologic response at 24 weeks.

Results

- SVR12: Sustained virologic response at 12 weeks.

- SVR24: Sustained virologic response at 24 weeks.

- 195 patients completed acute phase (Part A) and 97 patients enrolled (Part B) of the C-EDGE CO-STAR study.

- SVR12: Sustained virologic response at 12 weeks.

- SVR24: Sustained virologic response at 24 weeks.

- Reinfection occurred at a rate of 2.8 per 100 person-years (Figure 7).

- The timeframe for reinfection is shown in Figure 8.

Conclusions

- Patients enrolled in the long-term follow-up study were generally comparable to patients enrolled in the long-term follow-up study.

- Patients on OAT and patients on drug use.

Acknowledgments

- We extend our gratitude to the patients, their families, investigators, and site personnel who participated in this study.

References


