Effectiveness of 8-week sofosbuvir/ledipasvir in the adolescent chronic hepatitis C-infected patients.

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Abstract

BACKGROUND:
The sustained virological response (SVR) rate for the 12-week sofosbuvir (SOF)/ledipasvir (LVD) treatment of adolescent genotype-4 patients is high. The aim of this study is to evaluate 8 versus 12-week treatment efficacy and safety in adolescent genotype-4 patients.

PATIENTS AND METHODS:
In total, 157 chronic hepatitis C-infected adolescent patients (mean age 14±2 years, 62% males) were included in this study. All patients received a morning dose of SOF (400 mg)/LVD (90 mg) as a single tablet for 8 and 12 weeks. Laboratory and biochemical monitoring were performed at weeks 4 and 8, end of treatment (8/12) and 12 weeks after the end of treatment (SVR12).

RESULTS:
In total, SVR12 was 98% [95% confidence interval (CI): 96-100] for all treated patients. For patients treated for 12 weeks, SVR12 was 97.6% (95% CI: 96-101) (82/84 patients), and 98.6% (95% CI: 93-101) (72/73) patients for those treated for 8 weeks. For both regimens, no serious adverse effects, treatment discontinuation or cases of death were detected. The main adverse effects for the 8-week patient group were fatigue (2.8%), headache (1.4%), nausea (1.4%) and epigastric tenderness (1.4%). For the 12-week-treated group, adverse events were epigastric tenderness (1.2%), nausea (1.2%), diarrhoea (2.4%) and rash (2.4%). Three patients were lost to follow-up: two were in the 12-week treatment group and one was in the 8-week group. All of them reached end of treatment but were lost before SVR12. No relapsers were observed in either group.

CONCLUSION:
Eight weeks of treatment of SOF/LVD combination is equally effective and safe as 12 weeks in adolescent genotype-4 patients.

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