Predicting the Ability to Achieve a Sustained Virologic Response (SVR) in the First 12 Weeks: Results from the IDEAL Study


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Background
Hepatitis C virus (HCV) is a major cause of chronic liver disease and the leading indication for liver transplantation worldwide. Effective HCV treatment regimens are now available, but they are associated with significant adverse effects. Therefore, it is important to identify early on-treatment virologic factors associated with SVR, which may differ with various regimens and treatment durations.

Methods
The IDEAL study was a phase 3b, randomized, parallel-arm trial conducted at 118 academic and community centers in the United States. Patients (n = 3070) had similar baseline characteristics across the 3 treatment arms (Table 1). SVR rates ranging from 84% to 96% were observed in this large randomized study showing PPV for TW 2 is highly important to minimize exposure to these medications in patients who are unable to achieve SVR. Adherence based upon receiving 80% of both study treatments for 80% of the 48-week duration were PEG2b 1.5/20%, 38%; PEG2a/RBV, 64.4%, 31.5%, 40.9%. PPV for SVR at weeks 2, 4, 12, and 24 are shown in Figures 3 and 5.

Results
The proportions of patients who first attained undetectable HCV RNA levels for the first time at TWs 2, 4, 12, and 24 are shown in Figure 4. Adherence based upon receiving 80% of both study treatments for 80% of the 48-week duration were PEG2b 1.5/20%, 38%; PEG2a/RBV, 64.4%, 31.5%, 40.9%. PPV for SVR at weeks 2, 4, 12, and 24 are shown in Figures 3 and 5.

Conclusions
Results from this large randomized trial show for the first time that attaining undetectable HCV RNA at TW 2 is highly predictive of achieving SVR, and the number of patients who attain undetectable HCV RNA at TW 2 in each treatment arm is shown in Table 2.

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References

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