

measured with the unit of percent, was 34.1% in the treatment group and 33.8% in the placebo group (HR = 1.01; $P = 0.90$).

Regarding the secondary endpoints, serum aminotransferase, serum HCV-RNA, and histologic necroinflammatory scores, all decreased significantly ($P < 0.001$) with treatment. A SVR occurred in 18 treated subjects (3.5%) but in only one placebo subject.

The authors concluded that the long-term maintenance therapy is associated with decreases in serum HCV-RNA levels, serum ALT levels, and histologic necroinflammatory scores. Unfortunately, therapy was not associated with a reduction in clinical outcomes or in the progression of fibrosis.

IX. CONCLUDING REMARKS

A variety of endpoints can be used for assessing infection severity and for determining drug efficacy. The best account of endpoints for HCV infections is in the cited studies published in *New England Journal of Medicine*, and the Clinical Study Protocols that are published with these articles and that are available on the *Journal's* website. For HCV, these endpoints include indirect assessment of liver damage by way of serum aminotransferases (83), direct assessment of liver damage using liver biopsies, and the measurement of viral nucleic acids in the bloodstream.

⁸³McPherson PA, Pincus MR. Henry's clinical diagnosis and management by laboratory methods. 22nd ed. Philadelphia, PA: Elsevier Saunders; 2011.