with non-cirrhotic fibrosis (5.0% and 1.9%, respectively; P = .04), but not among subjects with cirrhosis (9.1% and 8.4%, respectively; P = .93).

The following provides another clear-cut example of analysis of subgroups within each study arm. The rate of progression to cirrhosis among subgroups with non-cirrhotic fibrosis was similar in the treatment and placebo arms (28.2% and 31.9%, respectively; P = .46). While there were no treatment benefits in terms of mortality or progression, in the context of the endpoint of *rate of progression*, the purpose of including this information was to provide a more detailed account of subgroup analysis.

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

IX. BIOMARKERS AND HEPATITIS C VIRUS

Biomarkers for use with HCV may be used for prognostic purposes, that is, whether an HCV infection will progress to include liver fibrosis or hepatocellular carcinoma (HCC) (53,54,55,56) as well as for predicting outcome to anti-HCV drugs (57,58).

The following concerns use of micro-RNA (miRNA) as a biomarker. The topic of miRNA was introduced at an earlier point in this book, in the account of the oncology clinical trial of Foekens et al. (59).

In a study of miRNA expression, Murakami et al. (60) found that the expression level of nine miRNAs were different in the sustained virological response (SVR) and non-responder (NR) groups. Liver biopsies were collected from each patient up to 1 week prior to administering therapy with the standard of care, that is, ribavirin plus

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