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Abstract 3247: SAME versus placebo for the reduction of serum AFP in patients with hepatitis C cirrhosis and moderately elevated AFP: A randomized, placebo-controlled, double-blind phase II trial

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Abstract

Background: Hepatocellular carcinoma (HCC) is a common complication of hepatitis C virus related cirrhosis (HCV-C). Alpha-fetoprotein (AFP) has been proposed as a biomarker of HCC risk. S-adenosylmethionine (SAME) is a food supplement that has an excellent safety profile. The use of SAME as a chemopreventive is based on abnormalities in methionine cycle (with decreased SAME levels) in patients with cirrhosis, increased risk of HCC in experimental animals deprived of SAME, and the prevention of liver cancer by SAME administration in animal models of chemically-induced HCC.

Methods: This was a prospective, randomized, placebo-controlled, double-blind phase IIb trial to determine if SAME (up to 2.4 grams/day) for 24 weeks reduced serum AFP levels in patients with HCV-C. Inclusion criteria: lab evidence of HCV-C (platelet count <150,000/mm³), AFP 15-100 ng/mL (normal less than 9 ng/mL). Exclusion criteria: non-HCV liver diseases, decompensated HCV-C (MELD>15), or history of, or mass suspicious for HCC. Primary outcome was decline in AFP between week 0 and 24. Secondary outcomes: change in other HCC-related markers (des-gamma carboxyprothrombin, AFP-L3), blood tests for HCV RNA, SAME metabolites, serum markers of oxidative stress, and quality of life.

Results: A total of 110 patients were enrolled and 87 completed study. After the 24-week treatment, AFP declined among patients receiving SAME (-1.9 ng/mL) and increased among patients receiving placebo (+5.9 ng/mL; p=0.16). Neither des-gamma carboxyprothrombin (DCP) nor AFP-L3 changed significantly with SAME treatment. There were no significant differences in serum HCV RNA between groups. Blood levels of SAME and S-adenosylhomocysteine (SAH) increased 3-5 fold among patients receiving SAME and were unchanged in placebo group (p<0.01). Serum glutathione and methionine did not change significantly. Several components of quality of life improved among patients receiving SAME. There were 5 serious adverse events in the placebo group and 7 in the SAME group; none were attributable to SAME.

Conclusions: SAME administration for 24 weeks in patients with HCV-C and elevated AFP did not decrease AFP significantly nor alter liver function. SAME significantly increased serum SAME and SAH levels, but did not alter serum glutathione level or serum markers of oxidative stress.

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