Treating chronic hepatitis C with milk thistle extract does not appear beneficial

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Use of the botanical product silymarin, an extract of milk thistle that is commonly used by some patients with chronic liver disease, did not provide greater benefit than placebo for patients with treatment-resistant chronic hepatitis C virus (HCV) infection, according to a study in the July 18 issue of *JAMA*.

Chronic hepatitis C virus infection affects almost 3 percent of the global population and may lead to cirrhosis, liver failure, and liver cancer. A large proportion of patients do not respond to certain treatments for this infection, and many others cannot be treated because of co-existing illnesses. "Thus, alternative medications with disease-modifying activity may be of benefit," according to background information in the article. Thirty-three percent of patients with chronic HCV infection and cirrhosis reported current or past use of silymarin for the treatment of their disease. Clinical studies that have evaluated milk thistle for a variety of liver diseases have yielded inconsistent results.

Michael W. Fried, M.D., of the University of North Carolina, Chapel Hill, and colleagues conducted a study to assess the use of silymarin for treating chronic HCV infection. The multicenter, placebo-controlled trial was conducted at 4 medical centers in the United States. Participants included 154 persons with chronic HCV infection and serum alanine aminotransferase (ALT; an enzyme that reflects liver function) levels of 65 U/L or greater who were previously unsuccessfully treated with interferon-based therapy. Enrollment began in May 2008 and was completed in May 2010, with the last follow-up visit completed in

March 2011. Participants were randomly assigned to receive 420-mg silymarin, 700-mg silymarin, or matching placebo administered 3 times per day for 24 weeks. The primary outcome measure for the study was a serum ALT level of 45 U/L or less (considered within the normal range) or less than 65 U/L, provided this was at least a 50 percent decline from baseline values. Secondary outcomes included changes in ALT levels, HCV RNA levels, and quality-of-life measures.

At the end of treatment, only 2 participants in each treatment group achieved the prespecified primary end point. The percentages of participants who achieved the primary end point were 3.8 percent in the placebo group, 4.0 percent in the 420-mg silymarin group, and 3.8 percent in the 700-mg silymarin group. The researchers also found that there was no statistically significant difference across treatment groups when changes in serum ALT levels from the beginning of the study to end of treatment were analyzed. Also, average serum HCV RNA levels did not change significantly during the 24 weeks of therapy.

There were no significant changes in physical or mental health components of quality-of-life scores, in chronic liver disease health-related quality-of-life assessments, or in depression scores in any group. Frequency of adverse events reported by individual patients also did not differ significantly among the treatment groups.

"In summary, oral silymarin, used at higher than customary doses, did not significantly alter biochemical or virological markers of disease activity in patients with chronic HCV infection who had prior treatment with interferon-based regimens," the authors conclude.

More information: *JAMA*. 2012;308[3]:274-282.