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File: ■ Artichoke (*Cynara scolymus*)
■ Cholesterol
■ Cardiovascular Disease

HC 120192-399

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RE: Potential Cholesterol-Lowering Effect of Artichoke Leaf Extract

Wider B, Pittler MH, Thompson-Coon J, Ernst E. Artichoke leaf extract for treating hypercholesterolemia. *Cochrane Database Syst Rev*. 2009;4:CD000335. DOI: 10.1002/14651858.CD003335.pub2.

The World Health Organization estimates that approximately 8% of all disease in developed countries is caused by elevated total cholesterol levels and that more than 60% of coronary heart disease cases are due to total cholesterol levels that exceed 3.8 mmol/L. According to National Cholesterol Education Program guidelines, approximately 30% of Americans have "undesirably high serum cholesterol levels." Standard treatment options for hypercholesterolemia include the use of statins; however, statin use is associated with adverse effects, such as carcinogenicity and liver damage. Therefore, treatment options without harmful side effects are desirable.

Artichoke (*Cynara scolymus*) leaf extract (ALE), which contains 1% caffeic acid derivatives, 1% flavonoids, and sesquiterpenes, has been proposed as one such treatment option. ALE has traditionally been used medicinally as a diuretic, a choleretic, and for liver problems (e.g., jaundice). In animal studies, ALE was shown to decrease plasma cholesterol and triglyceride levels and to prevent the development of atherosclerosis, likely because of its antioxidative effects. The cholesterol-lowering effects of ALE have also been observed in several case reports and uncontrolled studies in humans; however, the results of randomized controlled trials are needed to establish a cause-effect relationship. Thus, the objective of the present study was to review the results of randomized controlled trials (RCTs) that evaluated the cholesterol-lowering effects of ALE in hypercholesterolemic patients.

A literature search of the Cochrane Register of Controlled Trials, MEDLINE, EMBASE, AMED, and CINAHL through 2008 and of CISCOM through 2001 was conducted to identify RCTs that evaluated the use of oral preparations containing ALE as the only component in patients with hypercholesterolemia [defined as a total cholesterol level of at least 5.17 mmol/L (200 mg/dL)] in comparison with a placebo or reference medication. In addition, published and unpublished information was solicited from manufacturers of artichoke preparations and experts on the subject, and the bibliographies of the articles

retrieved were searched for pertinent trials. Three double-blind RCTs met the inclusion criteria and were included in this review.[1-3] Information on the methods used, patient characteristics, interventions, and results were systematically extracted from these articles. The primary outcomes of interest were reductions in total cholesterol, low-density-lipoprotein (LDL)-cholesterol, high-density-lipoprotein (HDL)-cholesterol, and triglyceride levels. The methodologic quality of the trials was evaluated by two reviewers, and any disagreements were resolved through discussion.

In the study by Bundy et al,[1] 75 men and women in the United Kingdom, most of whom were older than 50 years, received either 1280 mg ALE or placebo daily for 12 weeks. The total cholesterol level decreased by 42% in the ALE group but increased in the placebo group; the difference in change between groups was significantly different ($P = 0.025$). No significant differences in the changes in HDL, LDL, and triacylglycerol levels were observed.

In the study by Englisch et al,[2] which was conducted in Russia, 143 women aged 18-70 years received either 1800 mg ALE or placebo daily for 6 weeks. The total cholesterol level decreased by 18.5% in the ALE group and by 8.6% in the placebo group; the difference between groups was significant ($P < 0.00001$). The LDL-cholesterol level also decreased significantly more in the ALE group than in the placebo group ($P < 0.00001$); however, HDL and triacylglycerol levels were not significantly different between groups.

In the study by Petrowicz et al (abstract),[3] which was conducted in Germany, 44 healthy men and women aged 20-49 years received either 1920 mg ALE or placebo daily for 12 weeks. No significant effects of ALE were observed on serum HDL, LDL, total, or triacylglycerol levels in the total sample. However, total cholesterol levels decreased significantly in the subjects with an initial total cholesterol level of 230 mg/dL compared with the placebo group ($P = 0.015$).

All three studies reviewed were of "adequate methodological quality." The evidence from these three studies "suggests a modest positive effect of ALE on total and LDL cholesterol levels." However, the authors conclude that the evidence is "not compelling enough to recommend ALE as a treatment option for hypercholesterolemia." The limited data on safety suggest that the short-term use of ALE is associated with only mild and transient infrequent adverse events.

—Brenda Milot, ELS

References

[1]Bundy R, Walker AF, Middleton RW, Wallis C, Simpson HC. Artichoke leaf extract (*Cynara scolymus*) reduces plasma cholesterol in otherwise healthy hypercholesterolemic adults: a randomized, double blind placebo controlled trial. *Phytomed.* 2008;15:668-675.

[2]Englisch W, Beckers C, Unkauf M, Ruepp M, Zinserling V. Efficacy of artichoke dry extract in patients with hyperlipoproteinemia. *Arzneimittel-Forschung.* 2000;50:260-265.

[3]Petrowicz O, Gebhardt R, Donner M, Schwandt M, Kraft K. Effects of artichoke leaf extract (ALE) on lipoprotein metabolism in vitro and in vivo. *Atherosclerosis.* 1997;129:147.