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File: ■ Olive (*Olea europaea*) Leaf
■ Hypertension

HC 061111-432

Date: September 15, 2011

RE: Olive Leaf Extract Reduces Blood Pressure and Lowers Triglyceride Levels in Mildly Hypertensive Adults

Susalit E, Agus N, Effendi I, et al. Olive (*Olea europaea*) leaf extract effective in patients with stage-1 hypertension: comparison with Captopril. *Phytomedicine.* 2011 Feb 15;18(4):251-258.

Hypertension, or high blood pressure, increases the risk for cardiovascular disease, heart attack, and stroke. Due to the potential for adverse side effects and the cost of medications for treating hypertension, there has been great interest in finding natural alternatives that are safe and effective. The relatively high levels of monounsaturated fatty acids (MUFA) and antioxidants found in olive (*Olea europaea*) oil, the main energy source in the Mediterranean diet, may be at least partially responsible for its protective effect against heart disease. This double-blind, randomized, parallel and active-controlled clinical study was designed to confirm the antihypertensive effects of olive leaf extracts seen in previous studies by comparing its effectiveness with the prescription drug Captopril (Capoten®, an angiotensin converting enzyme [ACE]-inhibitor) in patients with stage 1 hypertension.

The study team conducted a trial using olive leaf extract EFLA943® (Benolea®; Frutarom Switzerland Ltd.; Reinach, Switzerland) and Captopril (Dexacap®; Dexa Medica; Tangerang, Indonesia). Participants all had stage 1 hypertension (defined as systolic blood pressure [SBP] of 140-159 mmHg and diastolic blood pressure [DBP] of 90-99 mmHg), and were asked to discontinue for the duration of the study any blood pressure medicine they were taking. The article does not state if the subjects were newly diagnosed or not. Those with renal, hepatic, or heart problems, a history of secondary hypertension, allergy to the treatments, and if pregnant or nursing were excluded.

A single-blind, 4-week run-in placebo period was performed to exclude patients who responded to diet alone. The participants were then randomly assigned to receive either 500 mg twice daily of olive leaf extract or 12.5 mg of Captopril twice daily in a double-blind, double-dummy fashion for 8 weeks. After 2 weeks, if SBP was already < 140 mmHg or there was a decrease of 5 mmHg from baseline, the dose of Captopril was titrated to 25 mg (2 active pills or 2 dummy pills [in the EFLA943 group] twice daily).

Blood pressure was recorded once per week and lipid levels at 4-week intervals. Patients were instructed to eat a low fat, low sodium diet and to record daily diets. Weekly visits were scheduled to take blood, review diets, administer and collect weekly allocations of the treatment, and facilitate compliance. The primary endpoint was a reduction in SBP after 8 weeks. Secondary endpoints were a reduction in SBP and DBP after each weekly visit and improvement of the lipid profile.

The researchers recruited 232 patients of whom 162 completed the study (average age = 51.5 ± 5.8 and 49.7 ± 6.8 years for the EFLA943 and Captopril groups, respectively; 85.4% and 87.6% female, respectively); however, 14 were incompliant with treatment, leaving 148 patients available for per protocol analysis. There was no intention-to-treat analysis reported. Sixteen people dropped out of the study due to various reasons, and 54 had no available post-treatment data. There were no differences in demographic data between the 2 groups. Dose increases were necessary in 28 and 35 patients in the Captopril and EFLA943 groups (dummy pills), respectively.

At the end of the 8-week period, patients in both the EFLA943 and Captopril groups experienced similar statistically and clinically significant reductions in both SBP (mean reduction: 11.5 ± 8.6 mmHg and 13.7 ± 7.6 mmHg, respectively) and DBP (mean reduction: 4.8 ± 5.5 mmHg and 6.4 ± 5.2 mmHg, respectively) when compared with levels before treatment ($P < 0.05$). The difference between groups was not significant for either SBP or DBP. There was also a large reduction in triglyceride levels in the EFLA943 group (11.90 ± 6.17 vs. -1.26 ± 43.31 mg/dl), which was even more pronounced in patients with triglycerides > 200 mg/dl. The result was not statistically significant due to insufficient power. This was an important finding, as having high triglyceride levels is a significant cardiac risk factor. A statistically significant decrease of low-density lipoprotein cholesterol (LDL) was also seen in the EFLA943 group ($P < 0.032$).

There were no clinically significant differences in laboratory safety parameters. A total of 1,057 adverse events were reported: 49.4% in the EFLA943 group and 50.6% in the Captopril group. The adverse events reported were described as mild (99.8%) and comparable between groups. The most common adverse events were coughing (4.6% in the olive group and 7.0% in the Captopril group) and vertigo (5.9% in the olive group and 6.3% in the Captopril group). Coughing is a known adverse side effect of ACE inhibitors, especially in middle-aged patients.

Based on the results of this study, the authors stated that the use of olive leaf extract at 1,000 mg daily reduces high blood pressure effectively and safely. They conclude that, "The anti-hypertensive activity of the extract was comparable to that of Captopril, given at its effective dose of 12.5 to 25 mg twice daily." They also note that the combined effect of reducing blood pressure, triglycerides, and LDL in those receiving olive leaf extract was an additional benefit.

—David Levine

The American Botanical Council has chosen not to reprint the original article.