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File: ■ African Oil Palm (*Elaeis guineensis*)
■ Mistletoe Fig (*Ficus deltoidea*)
■ Pre-diabetes

HC 051351-473

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RE: Evaluation of the Effectiveness and Safety of African Oil Palm and Mistletoe Fig Leaf Extracts in Adults with Pre-diabetes

Kalman DS, Schwartz HI, Feldman S, Krieger DR. Efficacy and safety of *Elaeis guineensis* and *Ficus deltoidea* leaf extracts in adults with pre-diabetes. *Nutr J*. April 1, 2013;12:36. doi: 10.1186/1475-2891-12-36.

People with pre-diabetes have an increased risk of developing diabetes, heart disease, and stroke. Pre-diabetes is defined as having fasting plasma glucose (FPG) concentrations of 100-125 mg/dl or 2-hr plasma glucose (PG) values during the oral glucose tolerance test (OGTT) of 140-199 mg/dl. During 2005-2008 in the United States, 35% of all adults ≥ 20 years of age and 50% of adults ≥ 65 years of age had pre-diabetes. Other than lifestyle modifications, there are no treatments for pre-diabetes. African oil palm (*Elaeis guineensis*) leaf extract reduced glycemia in rats. Mistletoe fig (*Ficus deltoidea*) leaf extract enhanced insulin-simulated glucose uptake in animals. Hence, the purpose of this randomized, double-blind, parallel-group study was to evaluate the safety and efficacy of African oil palm and mistletoe fig leaf extracts in adults with pre-diabetes.

Otherwise healthy adults (n = 30; aged 21-65 years) with pre-diabetes, a body mass index (BMI) of ≥ 25 kg/m^2 and < 40 kg/m^2, and a waist circumference of > 37 inches for men and > 31 inches for women participated in this study conducted in Miami, Florida. Specific exclusion criteria were not reported. Patients received either 500 mg of African oil palm leaf extract (OPLE), 1000 mg of OPLE, or 1000 mg of mistletoe fig leaf extract for 8 weeks. The treatments were prepared by Biotropics Malaysia Berhad; Selangor, Malaysia. Blood was drawn at 2, 4, and 8 weeks. Primary efficacy was measured by assessing changes in FPG and insulin via OGTT; and secondary efficacy was assessed by measuring changes in body weight and waist circumference.

At baseline, there were no statistically significant differences between groups. At 8 weeks, FPG was significantly decreased compared with baseline in the 500 mg OPLE group (P = 0.015); it approached significance in the 1000 mg OPLE group; and there was no change in the mistletoe fig group. Fasting plasma insulin values significantly decreased at 4 weeks and 8 weeks compared with baseline in the 500 mg OPLE group

only (P = 0.02 and P = 0.04, respectively). The 500 mg OPLE group had a significant increase in insulin sensitivity (P = 0.027) and a decrease in insulin resistance (P = 0.055). The mistletoe fig group had clinically significant decreases in total and low-density lipoprotein (LDL) cholesterol concentrations at 8 weeks (P = 0.049 and P = 0.012, respectively). The other groups had no significant changes in cholesterol. At 8 weeks, there was no significant change in body weight; even though at 4 weeks, there were increases in body weight in the 1000 mg OPLE group (P = 0.026) and in the 500 mg OPLE group (P = 0.080, non-significant). At week 8, waist circumference was significantly decreased in both the 500 and 1000 mg OPLE groups (P < 0.009 and P < 0.004, respectively), but not in the mistletoe fig group. Treatment compliance was 93%.

There were no significant differences in vital signs or lab safety tests. There were no serious adverse events (AEs). Only 1 of 18 AEs were considered possibly related to treatment (intermittent light-headedness); the specific treatment was not indicated. One patient in the 500 mg OPLE group dropped out due to an AE; however, the event was not described and was not considered possibly or probably related to treatment.

The authors conclude that 500 mg of OPLE had a clinically significant beneficial effect on fasting glucose levels in patients with pre-diabetes. They note that a larger population size would be needed to overcome the intra-subject variability that affected the results of the 1000 mg OPLE group. Both OPLE doses improved waist circumference, which is an important risk factor for metabolic syndrome. The authors chose not to comment on the mechanism of action because it was not evaluated in this study. They note that animal studies indicate that mistletoe fig helps with hyperglycemia; however, this clinical study did not demonstrate this effect in humans. Additional studies should be conducted to further evaluate the lipid-lowering effect of mistletoe fig. All 3 treatments were safe and well tolerated. This study is limited by the very small population size (n = 9-10 patients/group) and the lack of a placebo control. The findings need to be confirmed with a larger, placebo-controlled study.

—Heather S. Oliff, PhD

Referenced article can be found at http://www.nutritionj.com/content/pdf/1475-2891-12-36.pdf.