Effect of Black Tea Intake on Blood Cholesterol Concentrations in Individuals with Mild Hypercholesterolemia: A Diet-Controlled Randomized Trial

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ABSTRACT

Habitual intake of black tea has been associated with relatively lower serum cholesterol concentrations in observational studies. However, clinical trial results evaluating the effects of black tea on serum cholesterol have been inconsistent. Several factors could explain these mixed results, in particular, uncontrolled confounding caused by lifestyle factors (eg, diet). This diet-controlled clinical trial estimates the effect of black tea flavonoid consumption on cholesterol concentrations in 57 borderline hypercholesterolemic individuals (total cholesterol concentrations between 190 and 260 mg/dL [4.9 and 6.7 mmol/L]). A double-blind, randomized crossover trial was conducted in Minneapolis, MN, from April 2002 through April 2004 in which key conditions were tightly controlled to minimize possible confounding. Participants consumed a controlled low-flavonoid diet plus 5 cups per day of black tea or tea-like placebo during two 4-week treatment periods. The flavonoid-free caffeinated placebo matched the tea in color and taste. Differences in cholesterol concentrations at the end of each treatment period were evaluated via linear mixed models. Differences among those treated with tea vs placebo were 3.43 mg/dL (0.09 mmol/L) (95% CI −7.08 to 13.94) for total cholesterol, −1.02 mg/dL (−0.03 mmol/L) (95% CI −11.34 to 9.30) for low-density lipoprotein cholesterol, 0.58 mg/dL (0.02 mmol/L) (95% CI −2.98 to 4.14) for high-density lipoprotein cholesterol, 15.22 mg/dL (0.17 mmol/L) (95% CI −40.91 to 71.35) for triglycerides, and −0.39 mg/dL (−0.01 mmol/L) (95% CI −11.16 to 10.38) for low-density lipoprotein plus high-density lipoprotein cholesterol fraction. The low-density lipoprotein cholesterol to high-density lipoprotein cholesterol ratio decreased by −0.1 units (95% CI −0.41 to 0.21). No results were statistically or clinically significant. The intake of 5 cups of black tea per day did not alter the lipid profile of borderline hypercholesterolemic subjects significantly.
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TEA BREWED FROM *CAMELLIA SINENSIS* IS THE MOST commonly consumed beverage in the world after water.[1,2] It is rich in polyphenolic flavonoids that possess antioxidant, anti-mutagenic, anti-inflammatory, and anti-allergenic properties.[3] These flavonoids can also be hypocholesterolemic,[3-5] as shown in cell culture,[6-8] animal,[4,6,9-21] and observational[22-32] studies of black tea, the most commonly consumed tea in the United States. Clinical trial results, however, have been inconsistent.[33-39] Some randomized trials have found significant hypocholesterolemic associations between black tea consumption and lipid profiles,[33,36,39] while others have reported no effect on lipid profiles.[34,35,37,38] A review on the subject found limited evidence that tea has favorable effects on cardiovascular disease risk factors, including hypercholesterolemia.[40] It urged cautious interpretation of the results due to the small number of potentially biased trials, and emphasized the need for additional high-quality trials with longer-term follow-up.

Several factors can contribute to the mixed results of previous black tea and cholesterol trials, such as varying study duration, strength and brewing method of tea, average habitual tea consumption, and differences in participants' dietary habits. Earlier studies, with the exception of one clinical trial, have not rigorously controlled all of these factors.[36] The trial presented here addresses earlier deficits in the black tea and serum lipid literature by examining the effect of black tea beverage intake (5 cups/day, 700 mg tea solids/cup) on serum lipid concentrations using a standardized tea treatment and appropriate and consistent placebo in the presence of a completely controlled diet.

METHODS

Participants

Between April 2002 and April 2004, 1,500 individuals were recruited via television, radio, and print advertisements in Minneapolis and St Paul, MN. They were screened via telephone for eligibility before secondary screening at the University of Minnesota General Clinical Research Center (GCRC, currently the Clinical and Translational Science Institute), where a screening blood draw occurred. Basic eligibility criteria included age 45 to 65 years, borderline hypercholesterolemia (total cholesterol [TC] concentrations 190 to 260 mg/dL [4.9 to 6.7 mmol/L]), 35 to 65 mg/dL (0.9 to 1.6 mmol/L) of high-density lipoprotein cholesterol (HDL-C), and triglyceride (TG) concentrations <600 mg/dL (6.8 mmol/L). A slightly wider range than standard borderline hypercholesterolemia was utilized.[41] For additional inclusion/exclusion criteria, see Figure 1 (available online at www.andjrnl.org).

Of the 1,500 people initially screened, 400 (26.7%) were eligible and provided consent for secondary screening at the GCRC. Of these 400, 57 (14.3%) volunteers met all entry criteria, consented to participate, and were enrolled. Informed consent was obtained via a structured interview with the study coordinator before both screening and enrollment. The University of Minnesota, Twin Cities Institutional Review Board approved this study. The trial is registered at ClinicalTrials.gov (NCT01882283).

Study Design

At the end of a 1-week run-in period, 57 participants were block-randomized by sex using a computer-generated list to initial consumption of either 5 cups per day of black tea or placebo (tea-like) beverage. Block randomization was used to equally distribute potential differences within sexes (eg, metabolism) across randomization arms. Participants switched treatment assignments at the beginning of the second treatment period. Serum lipid values were measured at baseline and at the beginning and end of each treatment period. Research team members, participants, and analysts remained blinded until the final analysis was completed. Only the study statistician had access to randomization codes.

Intervention

The intervention consisted of 5 cups per day of black tea or a tea-like placebo for 4 weeks, plus a provided, low-flavonoid diet. The trial included two 41-day treatment periods and a 3-week washout period, which occurred between the treatment periods. Each treatment period was composed of 13 days of run-in time and 28 days of tea or placebo treatment. All participants consumed tea-like placebo during run-in periods. The weight-maintenance study diet was consumed throughout run-in and treatment periods, which allowed for a flavonoid washout from the self-selected diet consumed during the washout period. An overview of the entire study period and biological sample collection are described in Figure 2.

Black tea was selected for this intervention because it is the most commonly consumed form of tea in the United States. The selection of 5 cups of tea per day was based on its therapeutic potential and that, if therapeutic, this volume could be reasonably incorporated into a patient's daily routine. Significant effects on plasma cholesterol concentration, platelet aggregation, brachial artery reactivity, and oxidative damage, given response times, could occur within a 1-month period of tea intake, hence the 28-day treatment period.[3,42-45] The washout period duration allowed for re-equilibration of parent catechin and catechin metabolite concentrations to self-selected diet concentrations after tea intake.[46-50]

Tea Treatment and Placebo

Black tea and tea-like preparations arrived in identical individual serving packets from the Lipton Tea Company

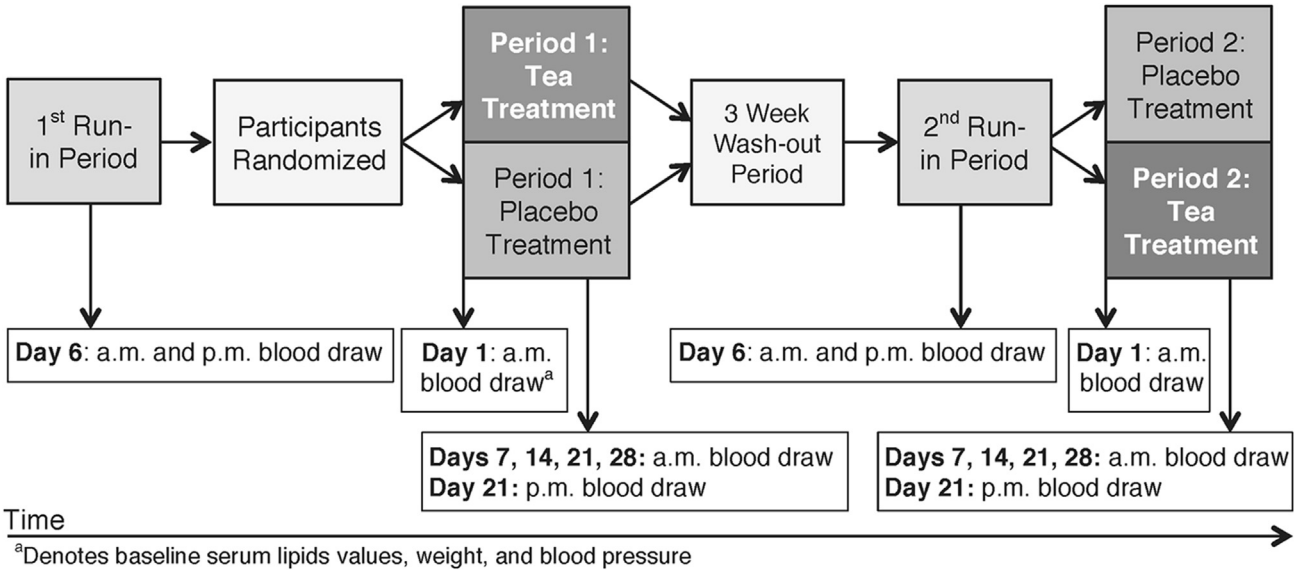

Figure 2. Crossover study design overview, including timing of biological sample collection points, in a study of the effect of 5 cups per day of black tea on serum cholesterol concentrations (n=57).