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**File: ■ Green and Black Tea (*Camellia sinensis*)**
**■ Lower Urinary Tract Symptoms**

**HC 071421-502**

**Date: August 15, 2014**

**RE: A Blend of Green and Black Tea Extract Improves Lower Urinary Tract Symptoms in Men**

Katz A, Efros M, Kaminetsky J, Herrlinger K, Chirouzes D, Ceddia M. A green and black tea extract benefits urological health in men with lower urinary tract symptoms. *Ther Adv Urol*. June 2014;6(3):89-96.

Lower urinary tract symptoms (LUTS) affect 50-90% of men over the age of 70. Symptoms include those associated with obstructive voiding (hesitation, straining, weak urine stream, and a feeling of incomplete emptying of the bladder) and irritation (urgency, frequency, and nocturia). Evidence from epidemiological studies suggests that green and black tea (*Camellia sinensis*) consumption is correlated with a reduction in incidence of LUTS. The goal of this randomized, double-blind, placebo-controlled trial (RCT) was to measure the effect of a proprietary blend of green and black tea aqueous extracts (AssuriTEA® Men's Health [AMH]; Kemin Foods L.C.; Des Moines, Iowa) on men with moderate-to-severe LUTS.

Men between the ages of 30 and 70 years old with moderate-to-severe LUTS were recruited for this 12-week study between December 2011 and July 2012. Severity of LUTS was based on the American Urological Association Symptom Index score (AUAss). Patients were excluded if they were taking medications for LUTS, antidepressants, anticholinergics, cholinergics, or dietary supplements for LUTS. In addition, patients were excluded if they had had surgery for benign prostatic hyperplasia (BPH), known renal or hepatic insufficiency, genitourinary cancer, consumed more than 1 cup of tea or 2 cups of coffee (*Coffea* spp.) per day, or had smoked regularly in the last 3 months.

Eligible patients were randomly divided into the following 3 groups: placebo (not described), 500 mg AMH, or 1000 mg AMH taken in 2 divided daily doses with meals for 12 weeks. The AMH product contains a minimum of 40% total phenols, 20% total catechins and theaflavins, 7-14% epigallocatechin-3-gallate, and a maximum of 12% caffeine. The primary outcome was the change in the AUAss. Average urinary flow rate (Qmean), maximum flow rate (Qmax), post-void residual volume (PVR), the quantitative Short Form-36 (SF-36) questionnaire score, and the International Index of Erectile Function (IIEF) score were measured at baseline (BL), 6, and 12 weeks. The

inflammatory marker C-reactive protein (CRP), cellular antioxidant protection (CAP-e), and ferrous antioxidant reducing capacity (FRAP) were measured at BL and 12 weeks. Evaluable patients were defined as those with ≥80% compliance as measured by pill count. To achieve a statistical power of 0.80 and a significance of P=0.05, the estimated required sample size was 11 completers per group. Data were analyzed with repeated measures analysis of variance.

Forty patients out of 46 completed the study with 12 in the placebo group, 15 in the 500 mg group, and 13 in the 1000 mg group. There were no statistical differences among the groups at BL. AUAss decreased significantly in the 1000 mg group over 6 and 12 weeks compared to BL (P = 0.035 and 0.008, respectively) but not in the placebo or 500 mg groups. The significance of the change in the 1000 mg group compared to placebo is not reported.

Compared to baseline, CRP increased significantly in the placebo and 500 mg groups over 12 weeks (P = 0.012 and 0.003, respectively) but not in the 1000 mg group. Qmean increased significantly in both the low- and high-dose AMH groups at 12 weeks when compared with the placebo group (P = 0.033 and 0.025, respectively), with a significant overall treatment effect (P = 0.01). PVR decreased significantly in the 1000 mg group at 6 weeks when compared to BL (P = 0.034) but not at 12 weeks. There was no significant change in Qmax, CAP-e, or FRAP in any group.

There were overall treatment effects in the IIEF sexual desire domain (P = 0.005), with a significant improvement in the 1000 mg group at 6 and 12 weeks (P = 0.041 and 0.015, respectively) compared to BL. Although there was no significant change in the overall SF-36 score, there was a significant treatment effect across the 3 groups in the physical function subsection (P = 0.051) after 12 weeks; for the 1000 mg group, the significance was P = 0.008 compared to placebo.

There were no significant changes in laboratory safety parameters. There was 1 case of deep vein thrombosis (500 mg group) which was deemed unrelated to the medication and 1 patient (500 mg group) withdrew due to fatigue which was deemed possibly related to the treatment. There was a decrease in diastolic blood pressure (BP) and systolic BP in the 1000 mg group at 6 weeks (P = 0.003 and 0.035) compared to placebo and a decreasing trend at 12 weeks (P=0.079).

In summary, 1000 mg AMH was effective in reducing the subjective AUAss in as little as 6 weeks (12/13 patients) and overall there was a 34.5% reduction in scores from BL to 12 weeks. Although the change in AUAss was not significant compared to placebo, the authors point out that a 3-point AUAss reduction produces clinically significant benefits and after deducting the effect size seen in the placebo group, there was still a clinically significant reduction (2.82 points) in the 1000 mg group. They note that the subjective AUAss improvements are supported by improvements in the objective measures of PVR, Qmean, and CRP. AMH was safe, well tolerated, and produced small positive benefits in BP. In contrast to many drug therapies, there were no negative sexual side effects and some patients reported improvements in sexual desire and physical functioning. The authors conclude, "AMH is an effective all-natural alternative for men seeking relief from LUTS."

A possible conflict of interest exists because funding for the study was provided by Kemin Foods, and 3 of the authors (Herrlinger, Chirouzes, and Ceddia) are employed at

Kemin Foods.

*–Cheryl McCutchan, PhD*

**Editorial Comment:**

Although the methodological quality of this study appears to be very good, there are some points that may trouble the critical reader. Compared to placebo, the change in the primary endpoint was not significant. Qmean and Qmax values declined between 6 and 12 weeks (almost back to BL levels) in the 1000 mg group. PVR values declined between BL and 6 weeks in both the 1000 mg and placebo groups, and then increased between 6 and 12 weeks in both groups. One cannot discern whether the deficiencies in data reporting are attributable to the authors or the journal editors (AUAss data are presented as a crude bar graph, the miniature CRP data table is incomprehensible, and the IIEF and SF-36 data are not provided).

Referenced article can be found at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4003843/.