

**Double-Blind, Placebo Controlled Evaluation of the Safety and Efficacy of Ephedra, Caffeine, and Salicin for Short Term Weight Reduction in Overweight Subjects.**

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**Introduction:** Obesity is approaching epidemic proportions in the Western world (1). Ephedrine and caffeine have previously been shown to aid weight loss in the overweight population (2). The intent of this study was to determine both the safety and efficacy of ephedra, caffeine and salicin with and without exercise, as an aid in weight loss. **Methods:** Twenty-four overweight (BMI 30.1± 2.42), healthy adult subjects were randomized into a prospective double-blind, placebo controlled eight week study. Sixteen subjects received treatment with ephedra 20mg, caffeine 200 mg, salicin 15 mg three times per day [Hydroxycut<sup>TM</sup>], whereas the other eight subjects received a maltodextrin placebo. Subjects underwent body composition analysis (7-site caliper), electrocardiograms, blood pressure, urinalysis, and serum multiple assay chemistry testing at baseline, week four and week eight. Participants were divided into three groups of eight subjects, Group A (treatment plus exercise), Group B (placebo, plus exercise), Group C (treatment, no exercise). Exercise consisted of three times per week, 30 minutes per session of cycling or stair climbing at 70% of heart rate maximum (Karvonen formula). All exercise was under the guidance of an exercise physiologist. All subjects had multiple dietary recalls for analysis of their diet by a registered dietitian. **Statistics:** Data for baseline comparisons were analyzed using the Kruskal-Wallis and Fisher exact test. Descriptive analysis was also carried out by the Kruskal-Wallis test. Changes over time within each group were analyzed using the Wilcoxon test. Bonferroni criteria were used to adjust multiple comparisons. **Results:** Group A experienced a significant reduction in body weight (-3.8 kg; p<0.01). No significant time trend for weight loss was found in either group B or C. Group C experienced a significant reduction in caloric intake (-680.2 kcal; p<0.05), while both groups A and B did not see any significant changes in dietary intake. There were no significant changes in blood pressure in any of the groups. There were no significant changes in EKG's, hydration status (measured via bioelectrical impedance and urinalysis), or serum blood chemistries over the eight-week study. **Discussion:** We hypothesized that the group receiving the ephedra, caffeine, salicin plus exercise (A) would lose the most weight. The study successfully showed that a combination of ephedra, caffeine and salicin coupled with moderate exercise resulted in a significant reduction in body weight. The fact there were no significant changes in EKG's, blood pressure, hydration, and serum multiple chemistries indicates that the combination of ephedra, caffeine and salicin plus exercise was safe and efficacious for promoting weight loss within the context of our study. This is the first ephedra/caffeine study to include the aspirin precursor salicin. Aspirin has been shown to potentiate the effects of ephedrine and caffeine (3). The decrease in food intake within the group only receiving treatment and no exercise deserves more attention. There is evidence that anaerobic and aerobic exercise, effect appetite differently. The combination of ephedra and caffeine has been shown to diminish appetite (4). Further studies are needed to identify whether different forms of exercise used in conjunction with the treatment will result in a greater weight loss. **References:** 1. PiSunyer FX. *Ann Intern Med* 119:655-660, 1993 ; 2. Daly P. et al. *Int J Obes Relat Metab Disord* 20:91-97, 1993 ; 3. Horton TJ. et al. *Int J Obes Relat Metab Disord* 20:91-97, 1996 ; 4. Tendra EW. *Int J Obes* 17:343-347, 1993.