

Title: Safety and effectiveness of an herbal dietary supplement containing ephedra (ma huang) and caffeine (guarana extract) when used in combination with a supervised diet and exercise intervention.

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Supplements containing ephedra alkaloids (ma huang) are widely used in the treatment of obesity, yet both their effectiveness and safety have been questioned. We examined the effects of an herbal supplement (S) containing ephedra alkaloids (20 mg) and guarana (200 mg caffeine) taken 3 times daily for 12 weeks vs a placebo (P). After medical screening, 21 obese men, (BMI ≥ 30 kg/m², 19-34 yr old) underwent a 12-week, caffeine-free, placebo-controlled (P=10, S=11), double blind, diet-exercise weight loss program. To ensure the target energy deficit of 3500 kcal/wk, daily diet records were analysed and exercise sessions were supervised. Resting HR and BP were measured on approximately 42 of the 84 d intervention and subjective side effects were noted daily. During the 12 weeks, resting HR was slightly elevated within the S group ($p < 0.05$), while resting BP was not affected, other reported side effects were mild and transient. No significant differences were seen in body composition (DEXA) or serum lipid profiles between groups. Mass decreased from 106.0 ± 11.5 to 96.9 ± 12.1 kg as did fat mass, 31.3 ± 5.3 to 25.8 ± 5.8 kg ($p < 0.05$) and % body fat, 29.4 ± 3.1 to $26.4 \pm 3.0\%$ ($p < 0.05$). Within the serum lipids there were no changes in total cholesterol, triglycerides, or HDL, however there was a decrease ($p \leq 0.05$) in the total cholesterol/HDL ratio and the LDL/HDL ratio. This study shows that the caffeine/ephedra S had only mild side effects when taken in a controlled manner, and did not influence the improvement in serum lipids. However, there was no impact on amount of adipose mass lost when diet and exercise are controlled, suggesting that any benefits of such ephedra and caffeine S are likely due to the anorectic effects.

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