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RE: Safety and Antioxidant Activity of a Pomegranate Ellagitannin-Enriched Polyphenol Extract


Pomegranate (*Punica granatum*) consumption has been associated with health benefits since ancient times, likely because of its potent antioxidant activity. The biologically active polyphenols responsible for greater than 90% of the antioxidant activity of pomegranate juice are known as ellagitannins. Extracts of pomegranate have been developed and marketed as dietary supplements to provide a simple and convenient vehicle for the consumption of the polyphenols found in pomegranate juice. Despite the commercial availability of pomegranate extracts, their safety in humans has not been evaluated. The objective of this study was to evaluate the safety and antioxidant activity of a pomegranate ellagitannin-enriched polyphenol extract (POMx™; POM Wonderful LLC, Los Angeles, CA) in humans. The no-observed-adverse-effect-level of POMx is 1500 mg/kg of body weight.

Generally healthy but overweight men (waist circumference > 40 inches) and women (waist circumference > 35 inches) were recruited for 1 of 2 four-week studies. The safety of POMx was studied at a clinical site in San Diego, California in 64 subjects aged 35-65 years, and the antioxidant activity of POMx was studied in 22 subjects aged 40-70 years at a clinical site in Denver, Colorado. POMx is a proprietary product standardized to contain at least 90% pomegranate hydrolyzable type polyphenols. Potential subjects receiving treatment for chronic disease related to oxidative stress, such as diabetes or hypertension, were excluded. At the San Diego site, the subjects ingested 1 or 2 POMx capsules daily, each of which provided 710 mg of extract and 435 mg of gallic acid equivalents (GAEs), or placebo (0 mg GAEs) in a blinded fashion. Blood and urine samples were collected at each of 3 visits to monitor electrolyte concentrations and liver and kidney function; blood pressure, pulse rate,
height, and weight were also measured. At the Denver site, the subjects ingested 2 POMx capsules daily, which provided 1000 mg of extract and 610 mg of GAEs, or placebo in a blinded fashion. Antioxidant status was determined via the measurement of plasma thiobarbituric acid–reactive substances (TBARS) before and after supplementation. All subjects were monitored for adverse events.

No serious adverse effects related to supplementation were reported at either clinical site. At the San Diego site, all of the subjects completed the study, and no significant supplementation-related changes were observed relative to placebo; none of the results of chemistry, hematology, or urinalysis testing was abnormal. At the Denver site, 22 of the 24 subjects completed the study. Body weight increased significantly (P = 0.05), body mass index (BMI) increased significantly (P = 0.010), and TBARS decreased significantly (P = 0.044) after 4 weeks of supplementation. No significant differences in any of the other measures of liver and kidney function were observed.

The results of these pilot studies indicate that the POMx supplement evaluated was both safe and efficacious in amounts up to 1420 mg/day for 4 weeks. The significant reduction in plasma TBARS was evidence of the antioxidant activity of POMx. Lower blood concentrations of TBARS are associated with a lower incidence of cardiovascular disease. The authors of the present study suggest that additional studies be conducted to "confirm the antioxidant properties of pomegranate ellagitannins administered as a dietary supplement."

—Brenda Milot, ELS

The American Botanical Council has chosen not to reprint the original article.