



## Point/Counter Point

### Prostate Health - Saw Palmetto

#### Introduction

Benign prostatic hyperplasia (BPH) is a non-cancerous swelling in the prostate gland of older men. It affects approximately 25 per cent of American Caucasians over the age of 50, with the direct cost of BPH in 2000 calculated to be \$1.1 billion (€ 0.9 billion). According to the European Association of Urology, 30 per cent of men older than 65 are affected by BPH.

#### POINT

Feb. 8, 2006 — **Saw palmetto is of no benefit in the treatment of benign prostatic hyperplasia (BPH)**, according to the results of a randomized, double-blind study published in the February 9 issue of *The New England Journal of Medicine*.

During the 1-year study, the change in AUASI scores was not significantly different between the saw palmetto and placebo groups (mean difference, 0.04 point; 95% confidence interval [CI], -0.93 to 1.01). Also, there were not any significant differences in maximal urinary flow rate (mean difference, 0.43 mL/minute; 95% CI, -0.52 to 1.38), prostate size, residual volume after voiding, quality of life, or serum prostate-specific antigen (PSA) levels. Both groups had a similar incidence of adverse effects.

#### Disclosure

Three authors have disclosed various relevant financial relationships with American Medical Systems, Intuitive Surgical, Merck, TAP, GlaxoSmithKline, Pfizer, and/or Merck.

#### COUNTER POINT

The results of this study have been called "*particularly puzzling*" by Dr. Andrew Shoa, from the US Council for Responsible Nutrition (CRN), given the number of previous studies that reported positive effects.

Previous studies using saw palmetto, including a meta-analysis of **18 clinical trials** (JAMA Vol. 280, pp. 1604-1609) and **21 clinical trials** (Cochrane Database of Systematic Reviews 2002 Iss. 3) had **reported positive results** for easing the **mild-to-moderate** symptoms.

The new double-blind randomized trial, published in the *New England Journal of Medicine* (Vol. 354, pp. 557-566), followed 225 men with an average age of 63 who had **moderate-to-severe** symptoms of BPH for one year. The men were divided into two groups, with one given 160 mg of Saw Palmetto twice a day (N=112), while the other group (N=113) received a placebo.

“Most of the official international monographs that recognize the benefits of saw palmetto do so for stage 1 and 2 of BPH, i.e. the **mild to moderate** range of symptoms.” “These include monographs from the German government and the World Health Organization,” said Blumenthal.

A reported 2.5 million Americans use saw palmetto with yearly sales of \$134 (€112) million, while in Germany over half of the nation's urologists prescribe plant-based extracts, of which saw palmetto is one of the main players.

### **Disclosure**

No relevant financial relationships disclosed.