

**International Workshop  
Summaries of Lectures  
Presented at the 2004 General Meeting  
of the BioBran Study Conference**

Regulation of the Defense Mechanism with Food

- Relationship between Tumor Dormant Therapy and Food Function -

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## Phytotherapy for Prostate Cancer – Hope or Reality?

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**[Purpose]** Clinical evaluation of a new phytotherapy protocol for prostate cancer that has become popular in Europe utilizing a combination of the nutraceuticals PROSTASOL, LENTIN PLUS and CURCUMIN COMPLEX. Anecdotal reports have claimed relief of metastatic pain, improvements in quality of life and reduction of the prostatic specific antigen (PSA) with the use of this product combination. Despite the lack of clinical data regarding safety and efficacy, an increasing number of patients in Europe and the United States are currently taking this herbal therapy.

**[Materials and Methods]** PROSTASOL and CURCUMIN COMPLEX are manufactured by medpro Holland B.V. in the Netherlands. PROSTASOL contains various sitosterols, quercetin and pygeum, as well as extracts from saw palmetto, ginseng, ginger, stinging nettle, scutellaria and reishi. CURCUMIN COMPLEX contains curcuminoids, bioperin and resveratrol. LENTIN PLUS is manufactured by Daiwa Pharmaceutical Co., Ltd. in Tokyo. It contains arabinoxylan derived from rice bran fermented with enzymes from Shiitake mushroom. A total of 96 patients with advanced metastatic prostate cancer (stage D3) were enrolled into a prospective clinical trial to evaluate possible toxic and beneficial effects of this phytotherapy regimen. After failing hormone-ablative therapy and with established disease progression, all patients received supplemental treatment with PROSTASOL (2880mg daily for the first month, 1800 mg per day for the second month, 1200 mg per day in the third months, and between 900 to 1200 mg from the fourth month on), CURCUMIN COMPLEX (3600 mg per day) and LENTIN PLUS (2000 mg per day) for a total follow-up of nine months. Hormonal therapy was continued throughout the trial to avoid the known withdrawal effect of anti-androgen on PSA. PSA was measured in all patients prior to phytotherapy, and then on a monthly basis. Side effects were monitored every two months during the entire study period. Effect of the therapy on tumor volume was evaluated by comparing bone scans, computed tomography scans and MRI scans before and after treatment.

**[Results]** Complementary treatment with PROSTASOL, CURCUMIN COMPLEX and LENTIN PLUS was associated with significant ( $p<0.05-0.01$ ) improvements in quality of life measures, reductions in patients' pain ratings ( $p<0.05-0.01$ ), a decline in PSA levels ( $p<0.01-0.001$ ), and a reduction in tumor volume in the majority of these patients. Side effects were mild. Increasing sensitivity of breast nipples and slight enlargement of the breast was seen in about 30-40% of the patients, and was most likely caused by phytoestrogenic effects of PROSTASOL. Dyspepsia was observed in about 5% of the patients, but occurred only in the first two weeks of treatment. There were no side effects on liver or kidney function, and there were no negative effects on the hematopoietic system from this regimen.

**[Conclusion]** This study verifies anecdotal reports of the beneficial effects of this combination therapy with PROSTASOL, CURCUMIN COMPLEX and LENTIN PLUS as a comparable alternative to current management regimens in hormone refractory prostate cancer. No conclusions can be drawn regarding the long-term effects of this new herbal therapy.