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File: ▪ **Prostate cancer**
▪ **PC - SPES**

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RE: Chinese Herb Formula Gives Relief in Prostate Cancer

Pfeifer BL, Pirani JF, Hamann SR, Klippel KF. PC-SPES, a dietary supplement for the treatment of hormone-refractory prostate cancer. *Br J Urol Intl*; 2000; Vol 85: 481-485.

Prostate cancer incidence is rising sharply due to the increasing age of the general population. This disease progresses to metastatic, incurable cancer in up to half of all cases. Once metastasis occurs, there is no cure for this cancer but some degree of tumor suppression may be achieved with hormonal therapy and orchidectomy (removal of one or both testes) or other drug therapies. In most patients, the cancer becomes hormone-refractory (resistant to hormone therapy); the median length of survival for patients at this stage of illness is reportedly six to 12 months.

Many experimental treatments for advanced prostate cancer are being studied but so far, none have been found curative. Those treatments offering short-term palliative benefits (which relieve discomfort but do not cure disease) often cause significant side effects. Therefore, many men with hormone-refractory prostate cancer consider alternative treatments including herbal medicines.

The herbal preparation PC-SPES (Botanic Labs, Brea, CA) has attracted much attention recently because of anecdotal reports that it relieves pain from metastases, reduces prostate-specific antigen (PSA) levels, and has no significant adverse side effects. PC-SPES is made up of a combination of eight herbs: Chrysanthemum flowers (*Chrysanthemum morifolium* Ramat., Asteraceae); reishi msuhroom (*Ganoderma lucidum* [Leyss, ex Fr.,] P. Karst. Ganodermataceae); licorice root (*Glycyrrhiza glabra* L., Fabaceae); dyer's woad (*Isatis indigotica* L., Brassicaceae); sanchi ginseng (*Panax pseudoginseng* Wallich, Araliaceae); *Rabdosia rebescens* (Blume) Hassk., Lamiaceae; baikal skullcap root, or huang qin (*IScutellaria baicalensis* Georgi., Lamiaceae*);* and saw palmetto fruit (*Serenoa repens* [Bartram} Small, Arecaceae).

There have been four clinical studies on PC-SPES to determine it's safety and efficacy. The studies include the one published by Pfeifer to assess the effects of PC-SPES on Quality of Life, PSA levels, and pain in 16 men with Stage D3 hormone-refractory prostate cancer.and three other studies which involved at least 23 patients and a study period of more than five months. Their conclusion is that "PC-SPES is a well-tolerated and active treatment for Androgen-Independent prostate cancer and the toxicity was mild (*Urology* 57(1); 2001: 122-126 (Harvard Medical School). The study by DiPaola, et al. suggests the estrogenic activity of PC SPES on in vitro assay.(DiPaola RS, Zhang H, Lambert GH *et al*. Clinical and

biological activity of an estrogenic herbal combination (PC-SPES) in prostate cancer. *N Engl J Med* 1998; 339: 785.)

For five months, all patients took three capsules of PC-SPES three times per day (TID), equaling a total daily dose of 2.88 grams. Patients were evaluated for pain, PSA level, and Quality of Life prior to (before supplementation) and at 4, 8, 12, 16, and 20 weeks following the start of the study. The before-supplementation values for all variables were used as the control values and all subsequent values were compared to them.

Study results showed that during PC-SPES supplementation, pain scores declined significantly ($p=<0.05$ - 0.01) from pre-supplementation scores. The 14 patients who took narcotics or nonsteroidal anti-inflammatory drugs for pain prior to the study showed a decrease of approximately 40% in their need for these pain medications after taking PC-SPES for 20 weeks.

Quality of Life scores improved significantly ($p=<0.05$ - 0.001) during PC-SPES use. Specifically, scores improved for physical, emotional, and functinal well-being but not for social well-being, which showed no significant change.

Highly significant ($p=<0.01$ - 0.001) reductions in PSA levels occurred during the study and 13 of the 16 patients had reductions of >50% from control levels. However, in three patients, these reductions (seen after four weeks on supplementation) were temporary in nature, rising to pre-supplementation levels by week 12 of supplementation. This suggests the possibility that their tumors became PC-SPES resistant. "On the other hand, eight of the 13 who responded to supplementation are still enjoying the beneficial effects of PC-SPES, long after the 20-week follow-up," report the authors. With a >50% reduction in PSA levels in most of the patients, the authors conclude that PC-SPES is effective in the treatment of Stage D3 hormone-refractory prostate cancer although the duration of this effect on PSA levels could not be determined from this study.

Patients reported only mild adverse effects including breast tenderness and indigestion. One patient developed recurrent deep vein thrombosis (DVT) that may or may not have been related to PC-SPES.

The findings of this study support the anecdotal reports regarding the benefits of PC-SPES and the authors conclude that "PC-SPES significantly reduces PSA levels and the pain of metastatic disease, thereby improving patients' quality of life without the detrimental side effects seen with other drug regimens." They note that achieving good Quality of Life is an appropriate therapeutic goal in hormone-refractory prostate cancer and that this goal can be attained with the use of PC-SPES.

— *Heather S. Oliff, Ph.D.*