

Hormonal dietary supplements might promote prostate cancer progression

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Hormonal components in over-the-counter dietary supplements may promote the progression of prostate cancer and decrease the effectiveness of anti-cancer drugs, researchers at UT Southwestern Medical Center have discovered.

The findings, which appear in today's issue of *Clinical Cancer Research*, reaffirm that patients should inform their doctors about any herbal or hormonal dietary supplements they are taking or considering taking. The researchers also recommend that documentation of supplement usage become part of routine health assessments for all patients, particularly cancer patients.

“Physicians need to ask their patients not only about the prescription drugs they may be taking, but – perhaps even more importantly – about the over-the-counter drugs and supplements, which may have a profound impact on certain health conditions,” said Dr. Claus Roehrborn, chairman of urology at UT Southwestern and one of the study's authors.

The researchers began their investigation when two patients being seen by UT Southwestern doctors developed aggressive prostate cancer within months of starting daily consumption of the same dietary supplement. Both men purchased the same product, one to develop stronger muscles and enhance sexual performance, the other to gain muscle.

Dr. Roehrborn, Dr. Shahrokh Shariat, a resident in urology and the study's lead author, and their colleagues analyzed the supplement, which

is not named in the study. They found that the product's label listed ingredients that were not present, misrepresented the concentrations of the ingredients present and failed to list all the steroid hormones contained in the product.

Hormone analysis revealed that the supplement contained testosterone and estradiol, a sex hormone. Researchers then tested the effect of the product on human prostate cancer-cell lines. The product proved to be a more potent stimulator of cancer-cell growth than testosterone. Additionally, attempts to stop the cancer-cell growth with increasing concentrations of the anti-cancer drug bicalutamide proved to be futile.

“Bicalutamide is an oral nonsteroidal anti-androgen used to treat prostate cancer,” Dr. Shariat said. “The fact that this supplement caused the drug to be less effective is very troubling.”

Based on the clinical data and cell culture experiments, the researchers filed an adverse event report with the Food and Drug Administration. The government agency in turn issued a warning letter to the manufacturers, which led to the removal of the product from the market.

“Unlike prescription and over-the-counter drugs, the law does not require nutritional supplements to undergo pre-market approval for safety and efficacy,” Dr. Shariat said. “The current FDA regulatory system provides little oversight or assurances that dietary supplements will have predictable pharmacological effects or even that product labels provide accurate information for consumers.”

The researchers say expanded research is needed to define the mechanism, safety and efficacy of common herbal and hormone dietary supplements.

“For most supplements efficacy is not established in randomized,

controlled trials. What is worse, safety is often equally poorly established,” said Dr. Roehrborn, who directs the Sarah M. and Charles E. Seay Center for Pediatric Urology.

An estimated 42 percent to 69 percent of U.S. adults use dietary supplements, at an estimated out-of-pocket expenditure of about \$34.4 billion, according to published reports cited in the study. Individuals often use supplements because they believe these natural products are safe and drug-free. The sale of androgenic steroids is exponentially increasing. In 2004, U.S. expenditures on testosterone supplements were estimated to be \$425 million.

“Given that testosterone supplements are in high demand, there is significant concern that supplements, in addition to the one we evaluated, may pose an urgent human health risk,” Dr. Shariat said.

Source: UT Southwestern Medical Center

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