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EMBARGOED for release at 5 p.m. ET Wednesday, April 3, 2013

On-and-off approach to prostate cancer treatment may compromise survival

Large, international trial finds intermittent androgen deprivation is not equivalent to continuous treatment

ANN ARBOR, Mich. — Taking a break from hormone-blocking prostate cancer treatments once the cancer seems to be stabilized is not equivalent to continuing therapy, a new large-scale international study finds.

Based on previous smaller studies, it looked like an approach called intermittent androgen deprivation therapy might be just as good as continuous androgen deprivation in terms of survival while meanwhile giving patients a breather from the side effects of therapy. In fact, researchers believed intermittent therapy might help overcome treatment resistance that occurs in most patients with metastatic hormone-sensitive prostate cancer.

But this new study, which treated 1,535 patients with metastatic prostate cancer and followed them for a median of 10 years, finds that's not the case. Results appear in the *New England Journal of Medicine*.

"We tried to see whether intermittent androgen deprivation is as good as continuous androgen deprivation, but we did not prove that. We found that intermittent therapy is certainly not better and moreover we cannot even call it comparable," says lead study author Maha Hussain, M.D., FACP, a prostate cancer expert oncologist at the University of Michigan Comprehensive Cancer Center.

The study was sponsored by SWOG, a National Cancer Institute-supported cancer clinical trials cooperative group.

In the study, men with metastatic hormone-sensitive prostate cancer were given an initial course of androgen deprivation therapy (hormone therapy), which is standard therapy for this disease. Patients with a stable or declining PSA level equal to or below a cut-off of 4 ng/ml were then randomly assigned either to continue or to discontinue the hormone therapy. Patients were carefully monitored with monthly PSAs and a doctor's evaluation every three months and therapy was resumed in the intermittent arm when PSA climbed to 20 ng/ml. The intermittent cycle continued on-and-off based on the PSA levels.

Survival among the two groups showed a 10 percent relative increase in the risk of death with intermittent therapy, with average survival of 5.8 years for the continuous group and 5.1 years for the intermittent group from the time of randomization.

Further, the researchers looked at quality of life between the two groups of patients. Initially the intermittent therapy group showed significant improvement in impotence and emotional function in the first three months and had improved trends in other aspects of quality of life compared to the continuous group. But these differences leveled off over time.

“The improvements in some aspects of quality of life that were observed early were not sustained after a few months as patients had to resume therapy,” says Hussain professor of internal medicine and urology at the U-M Medical School.

“If a patient is coming in with newly metastatic prostate cancer, hormone treatment continuously is the standard. If they wish to do intermittent treatment, they should be counseled that based on this data, their outcome might be compromised,” she adds.

Follow-up studies are investigating a new generation of anti-hormone treatments combined with current therapies in the hopes of increasing the treatment’s effectiveness.

Prostate cancer statistics: About 240,000 Americans will be diagnosed with prostate cancer this year and about 30,000 will die from the disease, according to the American Cancer Society.

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Funding: Primary funding for the SWOG-9346 trial was provided by the National Cancer Institute with additional support from Astra Zeneca.

Reference: *New England Journal of Medicine*, 368(14):1314-1325, April 4, 2013

SWOG is one of five cooperative groups within the National Cancer Institute’s (NCI’s) National Clinical Trials Network. SWOG designs and conducts multidisciplinary clinical trials to improve the practice of medicine in preventing, detecting, and treating cancer, and to enhance the quality of life for cancer survivors. The more than 4,000 researchers in the group’s network practice at more than 500 institutions, including 23 of the NCI-designated cancer centers as well as cancer centers in almost a dozen other countries. Formerly the Southwest Oncology Group, SWOG is headquartered at the University of Michigan in Ann Arbor, Michigan, (734-998-7140) and has an operations office in San Antonio, Texas, and a statistical center in Seattle, Washington. Learn more at swog.org.

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