Shortened course of radiation therapy safe and effective for men with high-risk prostate cancer

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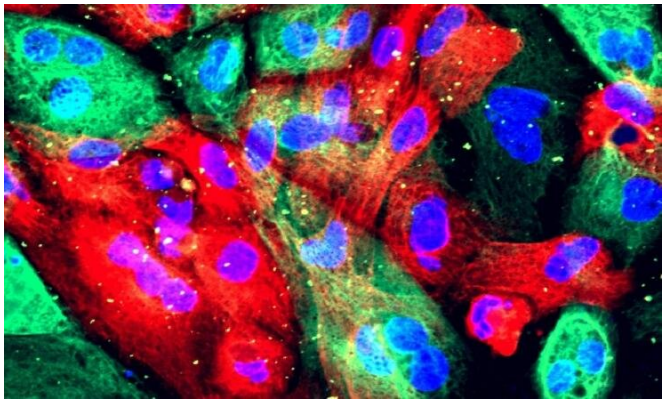

Prostate cancer cells. Credit: NIH Image Gallery

A new randomized study confirms that men with high-risk prostate cancer can be treated with five versus eight weeks of radiation therapy. The phase III clinical trial is the first to confirm the safety and efficacy of a moderately shortened course of radiation exclusively for patients with high-risk disease. Findings from the Prostate Cancer Study 5 (PCS5; NCT01444820) trial will be presented today at the American Society for Radiation Oncology (ASTRO) Annual Meeting.

"I think this trial will pave the way for patients with high-risk prostate cancer to be treated in five weeks instead of eight weeks. Many of these patients are still offered eight weeks of radiation therapy, but our trial found no benefit to the three extra weeks," said lead author Tamim M. Niazi, MD, an associate professor of oncology at McGill University and a radiation oncologist at Jewish General Hospital in Montreal. "Survival rates and side effects, both short-term and long-term, were similar with moderately shortened radiation therapy."

Large, randomized studies have confirmed the safety and efficacy of moderately shortened, or hypofractionated, radiation therapy for patients with low, intermediate or mixed-risk prostate cancer. The PCS5 trial is the first to show the same results specifically for men with high-risk disease.

"We asked, can we deliver radiation safely and effectively in less time so that our high-risk patients can finish their treatment faster?" said Dr. Niazi. "Hypofractionated treatment for prostate cancer decreases financial toxicity to patients, and it is completed in 25 days instead of the usual 38 to 40 days. That's three weeks of not having to come to the clinic—the transportation, parking costs, and just the time it takes away from a person's day-to-day life."

Roughly 15% of men diagnosed with prostate cancer have high-risk disease. These men face a higher likelihood than the lower-risk groups of their cancer recurring and/or spreading, and in those instances, they are more likely to die from their disease. The radiobiological properties of prostate cancer cells make them particularly sensitive to changes in radiation therapy fraction size, explained Dr. Niazi. "The whole idea behind this study—delivering moderately higher doses of radiation therapy per day in conjunction with long-term androgen deprivation therapy (ADT)—is that we can potentially maintain the same prostate cancer control rates as with standard fractionation, but in a shorter period of time."

In this multi-center Canadian trial, 329 patients were randomized to receive either standard/conventionally fractionated prostate radiation (76 Gy in 38 daily sessions) or moderately hypofractionated radiation (68 Gy in 25 daily sessions). Patients had to have high-risk disease, indicated by a higher Gleason score (8-10), Stage

T3a or higher, or PSA above 20, to be eligible for the study. All patients also received radiation to the pelvic lymph nodes and long-term ADT before, during and after radiation (median duration was 24 months).

Seven years after completing radiation therapy, the men who received hypofractionated or standard treatment had similar rates of recurrence and survival. Comparing patients who received accelerated versus standard treatment, researchers found no differences in overall survival (81.7% vs. 82%, p=0.76), prostate cancer specific mortality (94.9% vs. 96.4%, p=0.61), biochemical recurrence (87.4% vs. 85.1%, p=0.69), distant metastatic recurrence (91.5% vs. 91.8%, p=0.76) or disease-free survival (86.5% vs. 83.4%, p=0.50).

Side effects were also similar between the treatment arms. There were no grade 4 toxicities in either arm, and there were no significant differences in severe short-term or long-term genitourinary (GU) and gastrointestinal (GI) toxicities. Dr. Niazi said the team was pleasantly surprised that side effects were not significantly more pronounced with accelerated treatment.

While most patients with high-risk prostate cancer can benefit from the shorter course of radiation therapy, Dr. Niazi explained that some patients—for example, those who previously had prostate treatment (focal therapy), remote pelvic radiation therapy for other reasons or those with active inflammatory bowel disease, among other reasons were excluded from the trial and should still be treated with eight weeks of radiation.

Dr. Niazi outlined several next steps for this research. One path involves further reducing the number of fractions for patients with favorable high-risk disease, with an approach known as "ultra-hypofractionation" that could potentially involve only five treatments. Another path involves intensifying hormone therapy for patients with very high-risk disease. "We know the reason why patients unfortunately die of their cancer is because of metastasis, and the only way to reduce the rate of metastasis is to intensify systemic therapy," said Dr. Niazi. A final option is to study biomarkers/gene alteration to identify which patients should be treated more or less aggressively.

More information:
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