

The Lancet Publishes Sylvester-Led Study Defining New Standard of Care for Prostate Cancer Recurrence After Prostatectomy

Adding short-term hormone therapy and pelvic lymph node radiotherapy to standard of care prostatectomy surgical bed treatment benefits prostate cancer patients whose prostate-specific antigen (PSA) levels are rising post prostatectomy, according to an international study led by Alan Pollack, M.D., Ph.D., chair and professor of radiation oncology at Sylvester Comprehensive Cancer Center at the University of Miami Miller School of Medicine, and published in *The Lancet*.

“An increasing PSA after prostatectomy for prostate cancer is a hallmark of recurrence, which occurs on average in over 50% of patients with adverse surgical pathologic findings. The PSA indicates that the cancer has returned, but not where it is coming from – the prostate surgical bed, the pelvic lymph nodes, or elsewhere in the body,” according to Dr. Pollack.



Alan Pollack, M.D., Ph.D., led the study, which included patients in the U.S., Canada, and Israel.

Salvage radiotherapy is the only curative option for such patients, and the standard of care has been to treat the prostate surgical bed only. PSA recurrence after salvage radiotherapy has on average been over 50% over the subsequent five to 10 years. The SPPORT trial (RTOG/NRG Oncology 0534) was designed to test whether treatment intensification with the addition of short-term hormone therapy or short-term hormone therapy plus pelvic lymph node radiotherapy significantly reduces recurrence and the risk of cancer spread.

The National Cancer Institute-funded SPPORT trial was a study of men from 283 radiation oncology cancer treatment centers in the U.S. (including Sylvester), Canada, and Israel, who despite having had prostatectomy had PSAs of between 0.1 and <2.0 ng/mL. The men were randomly selected for prostate bed radiotherapy only; prostate bed plus four to six months of hormone therapy, also known as androgen deprivation therapy; or the two therapies with the addition of pelvic lymph node

radiotherapy.

Incremental Benefits

The investigators focused on five-year freedom from progression of prostate cancer as their primary outcome from the different treatment arms. They found that there was incremental benefit with each level of treatment intensification.



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The most intense treatment, which included the pelvic lymph nodes and androgen deprivation therapy, was significantly better than the other treatments. In an unplanned subgroup analysis based on the level of PSA on protocol entry, all patients – regardless of whether their PSAs were low or high – notably benefited from the addition of androgen deprivation therapy.

In the trial, five-year freedom from progression was 70.9% in

the group that received prostate bed radiotherapy only, versus 81.3% among those who also received androgen deprivation therapy.

Adding pelvic lymph node treatment also resulted in notable patient benefit to 87.4%, but that benefit was greatest for those who had higher PSAs at protocol entry.

New Standard of Care

The SPPORT trial confirms and extends the results of two other randomized trials of prostate bed radiotherapy plus hormone therapy, and is the first randomized study to show incremental benefit from the addition of pelvic lymph node radiotherapy, according to Dr. Pollack.

Dr. Pollack said that the SPPORT trial findings are consistent with newer PET imaging methods revealing that lymph node recurrences after prostatectomy are much greater than previously appreciated, and that the findings define a new standard of care for salvage radiotherapy.

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