Southwest
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# Landmark study shows adjuvant radiation after surgery helps prevent recurrence of localized prostate cancer

Results from a Southwest Oncology Group study show that radiotherapy given to men with locally advanced prostate cancer after their prostate gland is removed does not significantly reduce the risk of subsequent cancer spread to distant sites but significantly lowers the risk of the cancer recurrence compared to men who do not receive radiation.

The results were presented at a press conference today in conjunction with the publication of the study results in the Nov. 15, 2006, edition of the Journal of the American Medical Association.

The study involved 425 men who were on the study from 1988 through 1997, but whose health was followed through September 2005 for the purpose of long-term analysis. All the men in the study had surgery to remove their prostate gland and were found to be at a higher risk of cancer recurrence based on the extent of their cancer. These men were then randomly selected to receive either radiation or observation only during the study. There were 214 men in the group who received radiation and 211 who did not. The primary goal of the study was to determine if radiation would prevent subsequent spread of cancer to other areas of the body, generally to lymph nodes and bone.

Study results found a reduction in spread of cancer with radiation but the degree of reduction did not achieve statistical significance; radiation did reduce the risk of cancer coming back, reducing risk by about 40 percent. Additionally, men who had a low prostate-specific antigen (PSA) level after surgery and who received radiation had a significantly lower risk of subsequent development of a measurable PSA after surgery – a sign of possible cancer recurrence. PSA is a blood test that checks for a protein secreted by normal and cancerous prostate cells. When the prostate has been removed and the PSA level in the blood rises, it is generally a signal that cancerous cells are still present and growing.

"This is the second randomized study to evaluate the role of immediate post-operative radiation therapy on long-term results in the treatment of prostate cancer," said Gregory P. Swanson, M.D., co-investigator on the Southwest Oncology Group study known as **SWOG-8794**.

"These study results in this group of men with prolonged follow-up, considered in combination with the results of a larger European study, show that radiation significantly reduces the risk of prostate cancer recurrence after surgery. No other post-operative treatment has been shown to impact the risk of recurrence this dramatically. Patients who have a high risk of prostate cancer recurrence after surgery should be informed of these findings, especially before embarking on any other form of treatment, because no other treatment has been shown to have this degree of effectiveness," said Swanson, associate professor of Radiation Oncology and Urology at the University of Texas Health Science Center in San Antonio. He is one of several study coordinators who conducted the trial through the Southwest Oncology Group, one of the largest cancer clinical trials cooperative groups in the United States. The intergroup trial involved 108 institutions across the United States and Canada.

**Prostate cancer**

Prostate cancer is a type of cancer that forms in tissues of the prostate, a gland in the male reproductive system found below the bladder and in front of the rectum. Approximately 230,000 men are diagnosed with prostate cancer each year. According to the American Cancer Society, it is the second most common type of cancer in American men and the third leading cause of cancer death for men.

Surgically removing the prostate gland has been a long-standing treatment option for prostate cancer. Unfortunately, in some men, the cancer returns. Physicians have shown that there is an increased risk of this occurrence if:

- The cancer cells are outside the capsule of the prostate (a delicate covering around the prostate gland)
- The cancer cells are at the margin or edge of the prostate when it is removed.
- The cancer cells have spread to the seminal vesicles, two glands attached to the prostate that are responsible for making some of the fluid of the ejaculate.

Men who have undergone radical prostatectomy and who have any of these three features are felt to have a higher risk of the cancer returning. It is for this reason that these men were selected for this study.

For decades, one of the options offered to these men was radiation given after their operation. Previous studies, however, had conflicting results and may not have been as rigorously designed. As a result, there was no consensus among physicians as to whether radiation was beneficial. In addition to the large scale of this study and its head-to-head comparison of these treatments, this study had prolonged follow-up, allowing an evaluation of how the treatment affected the risk of cancer spreading and a man's long-term survival.

**Additional results**

While the study showed that radiation reduced the risk of prostate cancer coming back, there were a number of other important results. The study's primary goal was to find out whether radiation following removal of the prostate gland reduced a man's risk of developing cancer metastasis; that is, whether it prevented the cancer from spreading to other parts of the body.

The study found that radiation reduced this risk by 25 percent, extending the time to metastasis from 13.2 to 14.7 years, but this difference was not sufficiently different to be considered statistically significant. In the radiation group, 35.5 percent of the 214 patients were diagnosed with metastatic prostate cancer or died from any cause compared to 43 percent of the 211 patients in the observation group. Although no statistically significant improvement in survival was achieved, there were 83 deaths and a median survival of 14.7 years for the radiation group and 71 deaths in the observation-only group with a median survival of 13.8 years.

Adverse events (complications potentially related to treatment) were evaluated in patients in the two groups. The study found that there were more adverse events in the radiation group (23.8 percent) versus the no-radiation group (11.9 percent). Adverse events included rectal complications, urethral stricture and total urinary incontinence.

"This is a major advance in our efforts to control prostate cancer," said Ian M. Thompson, M.D., Professor and Chairman of Urology at the University of Texas Health Science Center at San Antonio and the principal investigator of the study. "The study shows that a man with this high-risk disease who receives radiation after surgery cuts in half his risk of disease recurrence. It also significantly reduces his risk of receiving hormonal therapy, a treatment with a wide range of side effects and complications in later years due to cancer recurrence. Complications were twice as common after radiotherapy and this is clearly part of the risk-benefit discussion between the patient and physician.

"There are several common approaches at this time to these men after surgery who are found to have a higher risk of recurrence," said Thompson. "One is to give immediate radiation, a second is to follow the PSA until it becomes detectable and then give radiation, and a third approach at some centers is to wait until spread of the disease is confirmed and then start hormonal therapy. In this study, a third of men who received no initial treatment subsequently were given radiation, most commonly due to a rising PSA. In some respects, this study speaks then to the differences in two approaches: radiotherapy after surgery versus radiotherapy at disease recurrence."

Laurence H. Baker, D.O., chairman of the Southwest Oncology Group and Professor of Medicine and Pharmacology at the University of Michigan, added, “Despite the relative frequency of prostate cancer accrual for this study, which included more than 400 patients, it required nine years of recruitment. While we are delighted with the positive results of this study, we remain concerned with the pace of clinical cancer research. We must do more to encourage urologists and radiation oncologists to participate in trials such as this.”

Dr. Thompson added, "Each one of these 425 men who participated in this National Cancer Institute-sponsored study is very special. Their participation in this study will have an impact on, and make better, the lives of tens of thousands of men in the U.S. alone each year. We should be very thankful to these wonderful gentlemen."

**About the Southwest Oncology Group**

The Southwest Oncology Group is one of the largest cancer clinical trials cooperative research groups in the United States. The Group is a network of more than 5,000 physician-researchers located at nearly 550 institutions. In addition to their regular medical practices, Group investigators work together on clinical trials funded by the National Cancer Institute, part of the National Institutes of Health, to prevent and treat cancer in adults. Among the Group's institutions are 17 of the NCI's 60 designated cancer centers. The Group enrolls nearly 7,200 patients each year and has about 120 clinical trials underway at any given time. The Southwest Oncology Group Headquarters Office is at the University of Michigan in Ann Arbor, Mich., the Operations Office is in San Antonio, Texas, and the Statistical Center is located at the Fred Hutchinson Cancer Research Center in Seattle, Wash.

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