

Title: A Randomized Trial Comparing Radical Prostatectomy with Watchful Waiting in Early Prostate Cancer

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What were the researchers trying to learn in this study?

They wanted to determine if performing radical prostatectomy to remove the prostate gland (and nearby lymph nodes) in men newly diagnosed with prostate cancer reduced the chance of death specifically due to prostate cancer and increased the overall chances of survival over the long-term. In this study watchful waiting included routine clinical exams 2 times a year for the first 2 years and every year thereafter. Clinical exams included blood tests, bone scans and chest x-rays.

What did they find?

After an average (median) follow-up of 6.2 years, 31 of the 348 men (8.9%) in the watchful waiting group died due to prostate cancer compared to 16 of 347 men (4.6%) in the radical prostatectomy group.

However, during that period, 31 men in the watchful waiting group and 37 men in the prostatectomy group died of other causes (including spread of cancer to other parts of the body). Final results indicated that 62 men in the watchful waiting group died of all causes versus 53 men in the radical prostatectomy group. This difference was not considered statistically meaningful.

Who was studied?

A group of 695 men who had been diagnosed with early prostate cancer at 14 cancer centers were randomly assigned to receive either radical prostatectomy or undergo watchful waiting.

All men were newly diagnosed with adenocarcinoma of the prostate (malignant tumor in the prostate gland) and all were in the early stages of the disease (T0d to T1c) with no metastases that is, the cancer had not spread to another part of the body.

All men were under 75 years of age, and were previously untreated for prostate cancer, with the exception of some having had a biopsy known as a transurethral resection. All men had no other history of cancer and had no obstruction of the upper urinary tract.

How was the study done?

The men were randomly divided into two groups: 347 had the radical prostatectomy surgery and 348 were placed in the watchful waiting group (that is, no immediate treatment was given). Both groups were divided among different medical centers.

Men in the watchful waiting group initially received no other form of treatment. If the disease progressed locally, surgery (transurethral resection) was performed to remove obstructive prostate gland tissue that interfered with urination.

The medium follow-up was 6.2 years. Follow-up examinations were conducted twice a year for the first two years and annually after that. A bone scan and chest x-ray were performed one year after randomization and then annually. After 1996, chest x-rays were performed annually for the first two years after randomization.

If follow-up studies showed either local progression of the disease or spread of the cancer to other parts of the body, men in both groups received various forms of treatment including hormonal therapy, external radiation therapy, and internal or implant radiation therapy (brachytherapy). Eventually, some men in the watchful waiting group did undergo the radical prostatectomy surgery.

What did researchers know before starting this study?

Radical prostatectomy has been widely used as treatment for early stage prostate cancer. However, observational studies have provided no conclusive data that indicates that radical prostatectomy is more effective than watchful waiting for prolonging survival in patients with early-stage prostate cancer.

Previous studies indicated that prostatectomy slowed the progression of prostate cancer more effectively than external radiotherapy. However, there was no observable increase in survival rate between the two treatments over a 20-year follow-up period.

Why did they do it?

This study was conducted primarily to evaluate the mortality rate specifically due to prostate cancer for men treated with radical prostatectomy upon initial diagnosis.

However, a secondary goal of the study was to observe both local disease progression and distant metastasis, and to evaluate overall mortality rate over a long term period between men who had the surgery upon initial diagnosis and those who did not.

What did the researchers say their study results mean?

The researchers concluded that radical prostatectomy performed during the early stages of prostate cancer reduced the mortality rate resulting specifically from prostate cancer. However, there was no significant difference in overall mortality rate between those who had the surgery versus those who underwent watchful waiting.

The authors also noted that this study was initiated before the practice of routine Prostate-Specific Antigen (PSA) screening began. This test determines if there is an elevated level of this protein in the blood, which can indicate the presence of prostate cancer. The authors concluded that use of this test to monitor cancer progression in early stage prostate cancer might further reduce the survival advantage of the surgery group as compared to the watchful waiting group.