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Original Contribution

Adjuvant Radiotherapy for Pathologically Advanced Prostate Cancer

A Randomized Clinical Trial

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Context Despite a stage-shift to earlier cancer stages and lower tumor volumes for prostate cancer, pathologically advanced disease is detected at radical prostatectomy in 38% to 52% of patients. However, the optimal management of these patients after radical prostatectomy is unknown.

Objective To determine whether adjuvant radiotherapy improves metastasis-free survival in patients with stage pT3 N0 M0 prostate cancer.

Design, Setting, and Patients Randomized, prospective, multi-institutional, US clinical trial with enrollment between August 15, 1988, and January 1, 1997 (with database frozen for statistical analysis on September 21, 2005). Patients were 425 men with pathologically advanced prostate cancer who had undergone radical prostatectomy.

Intervention Men were randomly assigned to receive 60 to 64 Gy of external beam radiotherapy delivered to the prostatic fossa (n = 214) or usual care plus observation (n = 211).

Main Outcome Measures Primary outcome was metastasis-free survival, defined as time to first occurrence of metastatic disease or death due to any cause. Secondary outcomes included prostate-specific antigen (PSA) relapse, recurrence-free survival, overall survival, freedom from hormonal therapy, and postoperative complications.

Results Among the 425 men, median follow-up was 10.6 years (interquartile range, 9.2-12.7 years). For metastasis-free survival, 76 (35.5%) of 214 men in the adjuvant radiotherapy group were diagnosed with metastatic disease or died (median metastasis-free estimate, 14.7 years), compared with 91 (43.1%) of 211 (median metastasis-free estimate, 13.2 years) of those in the observation group (hazard ratio [HR], 0.75; 95% CI, 0.55-1.02; *P* = .06). There were no significant between-group differences for overall survival (71 deaths, median survival of 14.7 years for radiotherapy vs 83 deaths, median survival of 13.8 years for observation; HR, 0.80; 95% CI, 0.58-1.09; *P* = .16). PSA relapse–free

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survival, 10.3 years for radiotherapy vs 3.1 years for observation; HR, 0.43; 95% CI, 0.31-0.58; *P*<.001) and disease recurrence (median recurrence-free survival, 13.8 years for radiotherapy vs 9.9 years for observation; HR, 0.62; 95% CI, 0.46-0.82; *P* = .001) were both significantly reduced with radiotherapy. Adverse effects were more common with radiotherapy vs observation (23.8% vs 11.9%), including rectal complications (3.3% vs 0%), urethral strictures (17.8% vs 9.5%), and total urinary incontinence (6.5% vs 2.8%).

Conclusions In men who had undergone radical prostatectomy for pathologically advanced prostate cancer, adjuvant radiotherapy resulted in significantly reduced risk of PSA relapse and disease recurrence, although the improvements in metastasis-free survival and overall survival were not statistically significant.

Trial Registration clinicaltrials.gov Identifier: NCT00394511

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