Follow-up of Prostatectomy versus Observation for Early Prostate Cancer.


Abstract

BACKGROUND: We previously found no significant differences in mortality between men who underwent surgery for localized prostate cancer and those who were treated with observation only. Uncertainty persists regarding nonfatal health outcomes and long-term mortality.

METHODS: From November 1994 through January 2002, we randomly assigned 731 men with localized prostate cancer to radical prostatectomy or observation. We extended follow-up through August 2014 for our primary outcome, all-cause mortality, and the main secondary outcome, prostate-cancer mortality. We describe disease progression, treatments received, and patient-reported outcomes through January 2010 (original follow-up).

RESULTS: During 19.5 years of follow-up (median, 12.7 years), death occurred in 223 of 364 men (61.3%) assigned to surgery and in 245 of 367 (66.8%) assigned to observation (absolute difference in risk, 5.5 percentage points; 95% confidence interval [CI], -1.5 to 12.4; hazard ratio, 0.84; 95% CI, 0.70 to 1.01; P=0.06). Death attributed to prostate cancer or treatment occurred in 27 men (7.4%) assigned to surgery and in 42 men (11.4%) assigned to observation (absolute difference in risk, 4.0 percentage points; 95% CI, -0.2 to 8.3; hazard ratio, 0.63; 95% CI, 0.39 to 1.02; P=0.06). Surgery may have been associated with lower all-cause mortality than observation among men with intermediate-risk disease (absolute difference, 14.5 percentage points; 95% CI, 2.8 to 25.6) but not among those with low-risk disease (absolute difference, 0.7 percentage points; 95% CI, -10.5 to 11.8) or high-risk disease (absolute difference, 2.3 percentage points; 95% CI, -11.5 to 16.1) (P=0.08 for interaction). Treatment for disease progression was less frequent with surgery than with observation (absolute difference, 26.2 percentage points; 95% CI, 19.0 to 32.9); treatment was primarily for asymptomatic, local, or biochemical (prostate-specific antigen) progression. Urinary incontinence and erectile and sexual dysfunction were each greater with surgery than with observation through 10 years. Disease-related or treatment-related limitations in activities of daily living were greater with surgery than with observation through 2 years.

CONCLUSIONS: After nearly 20 years of follow-up among men with localized prostate cancer, surgery was not associated with significantly lower all-cause or prostate-cancer mortality than observation. Surgery was associated with a higher frequency of adverse events than observation but a lower frequency of treatment for disease progression, mostly for
asymptomatic, local, or biochemical progression. (Funded by the Department of Veterans Affairs and others; PIVOT ClinicalTrials.gov number, NCT00007644.).

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