Radical prostatectomy versus observation for localized prostate cancer.


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Erratum in

Abstract

BACKGROUND: The effectiveness of surgery versus observation for men with localized prostate cancer detected by means of prostate-specific antigen (PSA) testing is not known.

METHODS: From November 1994 through January 2002, we randomly assigned 731 men with localized prostate cancer (mean age, 67 years; median PSA value, 7.8 ng per milliliter) to radical prostatectomy or observation and followed them through January 2010. The primary outcome was all-cause mortality; the secondary outcome was prostate-cancer mortality.

RESULTS: During the median follow-up of 10.0 years, 171 of 364 men (47.0%) assigned to radical prostatectomy died, as compared with 183 of 367 (49.9%) assigned to observation (hazard ratio, 0.88; 95% confidence interval [CI], 0.71 to 1.08; P=0.22; absolute risk reduction, 2.9 percentage points). Among men assigned to radical prostatectomy, 21 (5.8%) died from prostate cancer or treatment, as compared with 31 men (8.4%) assigned to observation (hazard ratio, 0.63; 95% CI, 0.36 to 1.09; P=0.09; absolute risk reduction, 2.6 percentage points). The effect of treatment on all-cause and prostate-cancer mortality did not differ according to age, race, coexisting conditions, self-reported performance status, or histologic features of the tumor. Radical prostatectomy was associated with reduced all-cause mortality among men with a PSA value greater than 10 ng per milliliter (P=0.04 for interaction) and possibly among those with intermediate-risk or high-risk tumors (P=0.07 for interaction). Adverse events within 30 days after surgery occurred in 21.4% of men, including one death.

CONCLUSIONS: Among men with localized prostate cancer detected during the early era of PSA testing, radical prostatectomy did not significantly reduce all-cause or prostate-cancer mortality, as compared with observation, through at least 12 years of follow-up. Absolute differences were less than 3 percentage points. (Funded by the Department of Veterans Affairs Cooperative Studies Program and others; PIVOT ClinicalTrials.gov number, NCT00007644.)

Comment in


Radical prostatectomy versus observation for localized prostate cancer. [Strahlenther Onkol. 2012]


Urological cancer: Radical lessons learnt from the prostate cancer PIVOT trial. [Nat Rev Clin Oncol. 2012]


Re: Radical prostatectomy versus observation for localized prostate cancer. [J Urol. 2012]


Commentary on: Radical prostatectomy versus observation for localized prostate cancer. [Urology. 2012]