A randomized trial comparing radical prostatectomy with watchful waiting in early prostate cancer.


Abstract

BACKGROUND: Radical prostatectomy is widely used in the treatment of early prostate cancer. The possible survival benefit of this treatment, however, is unclear. We conducted a randomized trial to address this question.

METHODS: From October 1989 through February 1999, 695 men with newly diagnosed prostate cancer in International Union against Cancer clinical stage T1b, T1c, or T2 were randomly assigned to watchful waiting or radical prostatectomy. We achieved complete follow-up through the year 2000 with blinded evaluation of causes of death. The primary end point was death due to prostate cancer, and the secondary end points were overall mortality, metastasis-free survival, and local progression.

RESULTS: During a median of 6.2 years of follow-up, 62 men in the watchful-waiting group and 53 in the radical-prostatectomy group died (P=0.31). Death due to prostate cancer occurred in 31 of 348 of those assigned to watchful waiting (8.9 percent) and in 16 of 347 of those assigned to radical prostatectomy (4.6 percent) (relative hazard, 0.50; 95 percent confidence interval, 0.27 to 0.91; P=0.02). Death due to other causes occurred in 31 of 348 men in the watchful-waiting group (8.9 percent) and in 37 of 347 men in the radical-prostatectomy group (10.6 percent). The men assigned to surgery had a lower relative risk of distant metastases than the men assigned to watchful waiting (relative hazard, 0.63; 95 percent confidence interval, 0.41 to 0.96).

CONCLUSIONS: In this randomized trial, radical prostatectomy significantly reduced disease-specific mortality, but there was no significant difference between surgery and watchful waiting in terms of overall survival.

Comment in

Radical prostatectomy may improve disease-specific mortality, but not overall survival compared with watchful waiting in early prostate cancer. [Cancer Treat Rev. 2003]

A randomized trial comparing radical prostatectomy with watchful waiting in early prostate cancer. [J Urol. 2003]

Prostatectomy or watchful waiting in prostate cancer. [N Engl J Med. 2003]
Early radical prostatectomy improves disease-specific but not overall survival. [J Fam Pract. 2003]
Prostatectomy or watchful waiting in prostate cancer. [N Engl J Med. 2003]
Prostatectomy or watchful waiting in prostate cancer. [N Engl J Med. 2003]
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PMID: 12226148 DOI: 10.1056/NEJMoa012794
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