10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer.


Abstract
Background The comparative effectiveness of treatments for prostate cancer that is detected by prostate-specific antigen (PSA) testing remains uncertain. Methods We compared active monitoring, radical prostatectomy, and external-beam radiotherapy for the treatment of clinically localized prostate cancer. Between 1999 and 2009, a total of 82,429 men 50 to 69 years of age received a PSA test; 2664 received a diagnosis of localized prostate cancer, and 1643 agreed to undergo randomization to active monitoring (545 men), surgery (553), or radiotherapy (545). The primary outcome was prostate-cancer mortality at a median of 10 years of follow-up. Secondary outcomes included the rates of disease progression, metastases, and all-cause deaths. Results There were 17 prostate-cancer-specific deaths overall: 8 in the active-monitoring group (1.5 deaths per 1000 person-years; 95% confidence interval [CI], 0.7 to 3.0), 5 in the surgery group (0.9 per 1000 person-years; 95% CI, 0.4 to 2.2), and 4 in the radiotherapy group (0.7 per 1000 person-years; 95% CI, 0.3 to 2.0); the difference among the groups was not significant (P=0.48 for the overall comparison). In addition, no significant difference was seen among the groups in the number of deaths from any cause (169 deaths overall; P=0.87 for the comparison among the three groups). Metastases developed in more men in the active-monitoring group (33 men; 6.3 events per 1000 person-years; 95% CI, 4.5 to 8.8) than in the surgery group (13 men; 2.4 per 1000 person-years; 95% CI, 1.4 to 4.2) or the radiotherapy group (16 men; 3.0 per 1000 person-years; 95% CI, 1.9 to 4.9) (P=0.004 for the overall comparison). Higher rates of disease progression were seen in the active-monitoring group (112 men; 22.9 events per 1000 person-years; 95% CI, 19.0 to 27.5) than in the surgery group (46 men; 8.9 events per 1000 person-years; 95% CI, 6.7 to 11.9) or the radiotherapy group (46 men; 9.0 events per 1000 person-years; 95% CI, 6.7 to 12.0) (P<0.001 for the overall comparison). Conclusions At a median of 10 years, prostate-cancer-specific mortality was low irrespective of the treatment assigned, with no significant difference among treatments. Surgery and radiotherapy were associated with lower incidences of disease progression and metastases than was active monitoring. (Funded by the National Institute for Health Research; ProtecT Current Controlled Trials number, ISRCTN20141297; ClinicalTrials.gov number, NCT00087976.)