Randomized prospective study comparing radical prostatectomy alone versus radical prostatectomy preceded by androgen blockade in clinical stage B2 (T2bNxM0) prostate cancer. The Lupron Depot Neoadjuvant Prostate Cancer Study Group.


Abstract

**PURPOSE:** Nonrandomized clinical trials have suggested that preoperative androgen deprivation can decrease the likelihood of positive surgical margins in patients with clinically localized prostate cancer. A multicenter prospective randomized trial compared radical prostatectomy alone to radical prostatectomy after 3 months of leuprolide acetate depot and flutamide in patients with stage cT2bNxM0 prostate cancer and a serum prostate specific antigen level less than 50 ng./ml.

**MATERIALS AND METHODS:** We randomized 149 patients to undergo androgen deprivation and 138 to undergo lymphadenectomy with (137) or without (1) prostatectomy. Of the 154 patients randomized to the surgery alone group 144 underwent pelvic node dissection with (138) or without (6) prostatectomy.

**RESULTS:** There was no statistically significant difference between the 2 groups in operating time, blood loss, need for transfusion, postoperative morbidity or length of hospital stay. There were 4 rectal and 2 ureteral injuries in the surgery alone group and none in the pretreatment group (p < 0.05). Patients who received androgen deprivation preoperatively had a significantly lower rate of capsule penetration (47% versus 78%, p < 0.002), positive surgical margins (18% versus 48%, p < 0.001) and tumor at the urethral margin (6% versus 17%, p < 0.01).

**CONCLUSIONS:** Long-term followup data will be needed to determine whether there will be a lower incidence of biochemical relapse as determined by prostate specific antigen, local recurrence or metastasis, with an improvement in patient survival.

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