

Intermittent Hormone Blockade for Localized Prostate Cancer.

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Abstract: No prospective randomized clinical trial (RCT) has demonstrated any form of radical local treatment to be superior to watchful waiting in the management of clinically localized prostate cancer. In the only prospective RCT comparing placebo to radical prostatectomy plus placebo, the Veterans Administration Cooperative Urological Research Group failed to demonstrate an overall survival benefit with a median follow-up of 23 years for patients undergoing prostatectomy compared to patients receiving no initial treatment (Iversen et al, Scand J Urol Nephrol, 1995, S172; 65-72). We report on 57 consecutive patients (mean age 66 years) in a community-based medical oncology practice, treated prospectively with intermittent hormone blockade. All patients had clinically localized or locally advanced prostate cancer and had refused conventional local treatment options. Treatment consisted of triple hormone blockade (THB) with an LH-RH agonist and antiandrogen (flutamide 250 mg TID or bicalutamide 150 mg QD) plus finasteride (5 mg QD) for a median duration of 13 months. All patients were then maintained on finasteride 5 mg daily. Mean pretreatment PSA was 12.59 ng/ml (range 3.40-100.0); mean Gleason score 6.54 (range 4-10); mean pretreatment testosterone 367 ng/dl. PSA declined to unmeasurable levels (less than 0.1 ng/ml) in all patients within a mean average of 4 months. At a mean follow-up of 55 months (range 38-125 months), mean PSA is 1.88 ng/ml (range 0-11) with a mean testosterone level of 396 ng/dl. No patient has received a second cycle of THB and no patient has received any form of local therapy. Five patients have PSA greater than 5.0 ng/ml. Cause specific survival is 100%. THB for 13 months followed by finasteride maintenance therapy is a promising alternative to watchful waiting in patients who refuse local therapy for prostate cancer.