



**Low and intermediate risk early prostate cancer (PC) managed with triple androgen blockade (TAB)**

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**Abstract:** Management of clinically localized PC remains controversial and treatment options now include radical surgery, radiation therapy, brachytherapy, androgen deprivation therapy (ADT), and watchful waiting. Moreover, there is no evidence from randomized clinical trials (RCT) to support a survival advantage for any form of radical local therapy (RLT). There is overwhelming evidence that all forms of RLT result in enduring decreases in quality of life (urinary incontinence, irritative voiding symptoms, erectile dysfunction, and/or bowel symptoms). According to numerous validated nomograms patients with low and intermediate risk PC (Gleason sum (GS) 7 or less, PSA <20, and clinical stages T1-T2a) are most likely to remain PSA failure-free at 5 and 10 year follow-up. As an alternative to RLT, we have been prospectively treating men who refuse local therapy with TAB. We report on 80 consecutive low and intermediate risk men (mean age 64, range 46-80) treated with a single cycle of TAB. Mean pre-treatment PSA was 7.75 (+/- SE 0.48), mean GS was 6.3 (+/- SE 0.1), and mean testosterone was 378 ng/dL (+/- SE 22). TAB consisted of 13 months of therapy with an LH-RH agonist and antiandrogens (bicalutamide 150 MG QD or flutamide 250 MG Q8H) plus finasteride 5 MG QD. All men were subsequently maintained on daily finasteride. At a median follow-up of 60 months (range 33-116) mean PSA was 2.25 ng/mL (range 0.004-8.300). Follow-up mean testosterone is 458 ng/dL (+/- SE 24). None of these men has received any local therapy or any additional ADT. Disease specific survival is 100%. All patients experienced typical and expected toxicity of ADT. Given the limited exposure to a single 13 month cycle of TAB, all toxicities were reversible. Self-reported libido and erectile function return to baseline in greater than 95% of patients. Physicians counseling newly diagnosed early PC patients should emphasize risk stratification, the absence of a proven survival advantage for RLT, and the known, usually permanent, toxicities of RLT's. We strongly encourage further investigation of TAB as primary therapy for early PC in the setting of a prospective clinical trial.