

Randomized Trial of Partial Gland Ablation with Vascular Targeted Phototherapy versus Active Surveillance for Low Risk Prostate Cancer: Extended Followup and Analyses of Effectiveness

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PURPOSE: The prospective PCM301 trial randomized 413 men with low risk prostate cancer to partial gland ablation with vascular targeted photodynamic therapy in 207 and active surveillance in 206. Two-year outcomes were reported previously. We report 4-year rates of intervention with radical therapy and further assess efficacy with biopsy results.

MATERIALS AND METHODS: Prostate biopsies were mandated at 12 and 24 months. Thereafter patients were monitored for radical therapy with periodic biopsies performed according to the standard of care at each institution. Ablation efficacy was assessed by biopsy results overall and in field in the treated lobe or the lobe with index cancer.

RESULTS: Conversion to radical therapy was less likely in the ablation cohort than in the surveillance cohort, including 7% vs 32% at 2 years, 15% vs 44% at 3 years and 24% vs 53% at 4 years (HR 0.31, 95% CI 0.21-0.46). Radical therapy triggers were similar in the 2 arms. Cancer progression rates overall and by grade were significantly lower in the ablation cohort (HR 0.42, 95% CI 0.29-0.59). End of study biopsy results were negative throughout the prostate in 50% of patients after ablation vs 14% after surveillance (risk difference 36%, 95% CI 28-44). Gleason 7 or higher cancer was less likely for ablation than for surveillance (16% vs 41%). Of the in field biopsies 10% contained Gleason 7 cancer after ablation vs 34% after surveillance.

CONCLUSIONS: In this randomized trial of partial ablation of low risk prostate cancer photodynamic therapy significantly reduced the subsequent finding of higher grade cancer on biopsy. Consequently fewer cases were converted to radical therapy, a clinically meaningful benefit that lowered treatment related morbidity.

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