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Editorial Open Access

Twenty Years in the Making: Overall Survival Increased with the Addition of Hormonal Therapy to Salvage Radiation Following Radical Prostatectomy

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Editorial

Prostate cancer is the leading malignancy in men and accounts for well over 25,000 deaths in the United States each year. About 40% of men diagnosed with localized prostate cancer will undergo prostatectomy, and a number of these will draw biochemical relapse long before metastatic disease can be found on scans. The proper management of these complex patients has challenged clinicians for decades. Dr. William U. Shipley of Massachusetts General Hospital and Harvard Medical School has contemplated one aspect of this problem for many years, designing a trial 20 years ago whose results were reported earlier this year at the 2016 Genitourinary Cancer Symposium.

Dr. Shipley's trial, RTOG 9601, randomized 760 American and Canadian men who had T3pN0 prostate cancer or T2pN0 with positive surgical margins, and elevated PSA following radical prostatectomy to two arms. In the study arm, patients received both radiation and 24 months of hormonal therapy with bicalutamide; and the comparator arm patients received radiation and placebo. Patient were treated on the trial from 1998 to 2003, and then followed for a median of 13.0 years. Patients had an elevated PSA level no higher than 4.0 ng/mL at study entry, with the median PSA being 0.6 ng/mL at baseline.

The results strongly favored adding hormonal therapy to radiation in this setting, with the strongest benefits being shown in patients with the highest risk disease (those with higher Gleason scores, positive surgical margins, and higher PSA levels at baseline). The primary study endpoint of overall survival revealed that at 10 years, 82% of patients who receive bicalutamide in addition to radiation were alive, as compared with 78% assigned to radiation with placebo. This corresponds to a 23% risk reduction in death (HR 0.77, 95% CI [0.59, 0.99]; p = 0.040).

The addition of hormonal therapy to salvage radiation in biochemical recurrence also significantly decreased the risk of metastasis, as well as the rate of disease related death. At the 10-year time point, the cumulative incidence of metastatic prostate cancer reached only 11% in those who received hormonal therapy, as compared with 19% in those who received placebo (HR 0.63, 95% CI [0.46, 0.87]; p=0.005). And, at 10 years, only 4.5% of patients treated with hormonal therapy had died of prostate cancer, while 10.1% of patients in the comparator arm had succumb to the disease (HR 0.49, 95% CI [0.32, 0.74]; p<0.001).

The number needed to treat to save one man dying from prostate cancer is only 12, a small investment given the low toxicity and affordability of hormonal therapy. These results, twenty years in the making, herald those of similar trials conducted in Britain and France, who results are still forthcoming. While awaiting those data, it seems prudent to consider the addition of extended bicalutamide to radiation in men with PSA-only recurrence following prostectomy, especially those with high risk features.