

From Dr. Tisman, received September 15, 2015:

Subject: Early Chemotherapy for Early Prostate Cancer

This abstract of a study which incorporated treatment of poor prognosis but localized prostate cancer is a positive one. It reveals that use of Taxotere/Prednisone chemotherapy with ADT and XRT is associated with increased survival at 4 years. I know most patients with localized prostate cancer want to stay away from chemotherapy however they should be aware that such therapy does impact survival.

A phase III protocol of androgen suppression (AS) and 3DCRT/IMRT versus AS and 3DCRT/IMRT followed by chemotherapy (CT) with docetaxel and prednisone for localized, high-risk prostate cancer (RTOG 0521).

Subcategory: Prostate Cancer

Category: Genitourinary (Prostate) Cancer

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Abstract Disclosures

Abstract:

Background: High-risk, localized prostate cancer (PCa) patients have a relatively poor prognosis. We hypothesized that the addition of adjuvant docetaxel and prednisone to long-term (24 month) AS and radiation therapy (RT) would improve overall survival (OS).

Methods: RTOG

0521 opened December 2005 and closed August 2009 with targeted accrual of 600 cases. It was designed to detect improvement in 4-year OS from 86% to 93% with a 51% hazard reduction (HR = 0.49). Under a 0.05 1-sided type I error and 90% power, at least 78 deaths were required to analyze the OS endpoint. Patients had 1) Gleason (GI) 7-8, any T-stage, and PSA > 20, or 2) GI 8, ≥ T2, any PSA, or 3) GI 9-10, any T-stage, any PSA. All had PSA ≤ 150. RT dose was 75.6 Gy. CT consisted of 6, 21-day cycles of docetaxel + prednisone starting 28 days after RT.

Results: Of 612 enrolled, 50 were excluded for eligibility issues, leaving 562 evaluable. Median age = 66, median PSA = 15.1, 53% had GI 9-10, 27% had cT3-4. Median follow-up = 5.5 yrs. 4-yr OS rates were 89% [95% CI: 84-92%] for the AS+RT arm and 93% [95% CI: 90-96%] for the AS+RT+CT arm (1-sided p = 0.03, HR = 0.68 [95% CI: 0.44, 1.03]). There were 52 centrally-reviewed deaths in the AS+RT arm and 36 in the AS+RT+CT arm, with fewer deaths both due to PCa/treatment (20 vs 16) and due to other causes/unknown (32 vs 20) in the AS+RT+CT arm. 5-yr disease-free survival rates were 66% for AS+RT and 73% for AS +RT+CT (2-sided p = 0.05, HR = 0.76 [95% CI: 0.57, 1.00]). There was 1, Gr 5 unlikely-related adverse event (AE) in the AS+RT arm and 2, Gr 5 possibly/probably-related AEs with AS+RT +CT.

Conclusions: For high-risk, localized PCa, adjuvant CT improved the OS from 89% to 93% at 4 years. Toxicity was acceptable. This trial was designed with a short OS assessment period and additional follow-up is warranted to determine the long-term benefit of CT to the current standard of care of long-term AS+RT.

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