

MEETING DATES: OCTOBER 18-21, 2015 EXHIBIT DATES: OCTOBER 18-20, 2015 HENRY B. GONZÁLEZ CONVENTION CENTER SAN ANTONIO





Duration of Androgen Deprivation in Locally Advanced Prostate Cancer: Long-Term Update of NRG Oncology/RTOG 9202

C. A. F. Lawton¹, J. J. Dignam², G. E. Hanks³, H. Lepor⁴, D. Grignon⁵, H. D. Brereton⁶, M. Bedi¹, S. A. Rosenthal⁷, K. L. Zeitzer⁸, V. M. Venkatesan⁹, E. M. Horwitz³, T. M. Pisansky¹⁰, H. Kim¹¹, M. B. Parliament¹², Y. Kwok¹³, M. Roach III¹⁴, X. Lin¹⁵, and H. M. Sandler¹⁶

¹Medical College of Wisconsin, Milwaukee, WI, ²NRG Oncology Statistics and Data Management Center, Philadelphia, PA, ³Fox Chase Cancer Center, Philadelphia, PA, ⁴NYU Langone Medical Center, New York, NY, ⁵Indiana University, Indianapolis, IN, ⁶Northeast Radiation Oncology Center, Dunmore, PA, ⁷Radiation Oncology Center, Sacramento, CA, ⁸Einstein Medical Center, Philadelphia, PA, ⁹London Regional Cancer Program, London, ON, Canada, ¹⁰Mayo Clinic, Rochester, MN, ¹¹Wayne State University-Karmanos Cancer Institute, Detroit, MI, ¹²Cross Cancer Institute - Alberta Health Services, Edmonton, AB, Canada, ¹³University of Maryland School of Medicine, Baltimore, MD, ¹⁴University of California, San Francisco, San Francisco, CA, ¹⁵University of Chicago, Chicago, IL, ¹⁶Cedars-Sinai Medical Center, Los Angeles, CA

Purpose



- To determine whether adding 2 years of adjuvant androgen-deprivation therapy (ADT) improves outcome for patients treated with ADT before and during radiation therapy (RT)
- This analysis will serve as a final update on outcomes and toxicities



Methods



- Patients with biopsy-proven prostate cancer with cT2c-T4 disease and no extra pelvic lymph node involvement and prostate-specific antigen (PSA) < 150
- No distant metastasis
- KPS ≥ 70
- Institute Review Board (IRB) approval and informed consent signed
- No prior androgen deprivation therapy (ADT), chemo or radiation therapy (RT) allowed

Treatment



- ADT started 2 months prior to RT and continued until RT completed
- ADT= flutamide (250 mg) orally 3x daily and goserelin (3.6 mg) injected subcutaneously monthly
- RT= conventional RT to the pelvis "4 field tech" to 44-46Gy (> 4MV) followed by a "cone down" to the prostate to 65-70Gy (isocenter dose)
- Patients then randomized to no further ADT (short-term ADT) vs 24 additional months of monthly goserelin (long-term ADT)



Results



- Study accrual dates: 6/92-4/95
- N=1554 patients registered, 1520 eligible w/ follow-up
- Median follow-up: 20 years
- Endpoints:
 - DFS (Disease Free Survival) = Primary Endpoint
 - OS (Overall Survival)
 - LP (Local Progression)
 - DM (Distant Mets)
 - BF (Biochemical Free Survival)¹
 - DSS (Disease Specific Survival)
 - Death due to dz, treatment or unknown cause after DM
- Toxicity: No difference in urinary toxicity and minimal difference in bowel toxicity



Conclusions



- Compared to STAD, LTAD improves:
 - Disease Free Survival
 - Local Progression
 - Distant Metastasis
 - bNED Survival
 - Disease Specific Survival
- For LTAD, 10% risk reduction, ~3% absolute OS difference was not statistically significant
- Patients who have locally advanced prostate cancer should receive radiation therapy and long term ADT



Discussion



- Comparison to other studies
 - EORTC 22961 6 months vs 36 months ADT:
 - 36 months improved Clinical Progression Free Survival
 - PCS IV (Canadian Trial) 18 months vs 36 months:
 - No difference in OS, DSS or Distant Mets
 - DART01/05 GICOR Trial 4 months vs 28 months + high dose RT:
 - OS, DM Free Survival & bNED improved with 28 months

