progression-free survival. Radiation with concurrent cisplatin remains the standard of care in these patients.

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LBA5

Short Term Androgen Deprivation Therapy Without or With Pelvic Lymph Node Treatment Added to Prostate Bed Only Salvage Radiotherapy: The NRG Oncology/RTOG 0534 SPPORT Trial

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Purpose/Objective(s): To determine in a three-arm randomized trial whether there are incremental gains in freedom from progression (FFP) from the addition of 4-6 months of short term androgen deprivation therapy (STADT) using antiandrogen plus an LHRH agonist, without or with pelvic lymph node treatment (PLNRT), to prostate bed salvage radiotherapy (PBRT).

Materials/Methods: Patients were randomized to PBRT alone (Arm 1), PBRT + STAD (Arm 2), and PLNRT + PBRT + STAD (Arm 3). The FFP primary endpoint included PSA nadir+2, clinical failure, or death from any cause, with censoring for secondary salvage therapy initiated prior to these events. The sample size provided 90% statistical power to detect a 10% absolute FFP improvement at 5 yr in Arm 2 compared to Arm 1 and a 10% absolute improvement at 5 yr in Arm 3 compared to Arm 2 at an overall alpha level of 0.025. On the third planned interim analysis for efficacy and futility based on 1191 eligible patents with 5 yr minimum follow-up, the treatment arms were compared in a stepwise approach to determine if the Haybittle-Peto (HP) threshold boundary of $p < 0.001$ (one sided) was crossed. Futility evaluation tested the alternative hypotheses at $p < 0.001$. Adverse events were graded using CTCAEv3.0.

Results: There were 1792 patients enrolled from 2008 − 2015. Median follow-up for those living is 5.4 yr. Ineligible patients included 18, 17, and 21 in Arms 1, 2, and 3. The patient and tumor characteristics for the 1736 eligible patients include a median age of 64 yr (range 39-84), black in 13%, baseline Zubrod status of 0 in 93%, seminal vesicle involvement in 15%, pre-radiotherapy PSA of ≤1.0 ng/ml in 89%, Gleason score < 8 in 83%, and pT2 margin positive or pT3 in 72%. Arms 1, 2, and 3 had 5 yr FFP rates of 71.1%, 82.7% and 89.1%. Arm 3 had the highest rate compared to Arm 1 ($p < 0.0001$), exceeding the HP boundary. The hazard ratio (HR) between arms 3 and 1 was 0.44 (95% CI: 0.32-0.59). Arm 3 was then compared to Arm 2, yielding a difference of 6.4% ($p = 0.0063$) and a HR of 0.71 (95% CI: 0.51-0.98). In all eligible patients followed for up to 8 years, there were 45, 38 and 25 patients who developed distant metastasis (DM) in Arms 1, 2 and 3. Without second salvage censoring, the DM hazard ratio for Arm 3 vs Arm 1 was 0.52 (95% CI: 0.32-0.85) and for Arm 3 vs. Arm 2 was 0.64 (95% CI: 0.39-1.06). With IMRT use in 87% of cases, highest late grade 3+ toxicity was observed in 4.3%, 4.9% and 6.0% for renal/genitourinary events and 0.7%, 0.4%, and 1.1% for gastrointestinal events in Arms 1, 2, and 3.

Conclusion: This is the first report of the primary endpoint and is the first randomized trial to show significant incremental improvements in FFP going from PBRT only to PBRT+STAD to PLNRT+PBRT+STAD. The addition of PLNRT resulted in early, meaningful, reductions in failure. Follow-up of patients will further elucidate the magnitude of the differences between arms 2 and 3.

LBA6

Plasma Circulating Tumor HPV DNA for the Surveillance of Cancer Recurrence in HPV-associated Oropharyngeal Cancer

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Purpose/Objective(s): To assess the performance of plasma circulating tumor HPV DNA (ctHPVDNA) as a surveillance blood test in patients with p16 positive oropharyngeal squamous cell carcinoma (OPSCC).

Materials/Methods: A prospective biomarker trial was conducted in 89 patients with p16 positive OPSCC who had no evidence of distant metastatic disease at baseline. All patients received definitive chemoradiotherapy (CRT) with 78 receiving de-intensified CRT on clinical trial (60Gy). Remaining patients received standard CRT (70Gy). All patients had a 3 month post-CRT PET/CT and were thereafter surveilled with clinical examinations every 2 - 4 months for years 1 - 2, then every 6 months for years 3 - 5. Chest x-rays or chest CT's were performed every 6 months. Blood specimens were collected at baseline (58/89), weekly during treatment (30/89), and with each follow-up visit (89) for plasma circulating nucleic acid extraction (Qiagen). Multianalyte droplet digital PCR assays were developed for ultra-sensitive detection of ctHPVDNA -16, -18, -31, -33, and -35 DNA on the Bio-Rad QX200 platform. Additional imaging was obtained if ctHPVDNA became detectable in the blood. Sensitivity, specificity, negative predictive value (NPV), and positive predictive value (PPV) of ctHPVDNA testing at detecting recurrence were calculated. Events were defined as recurrence after the 3 month post-CRT PET/CT.

Results: Clinical characteristics were the following: 89% T0-2, 80% N2, 80% never/≤ 10 pack years. Mean f/u was 19.8 months (range 3.7 − 44.7). Baseline ctHPVDNA was detectable in 51/58 (88%), with a median value of 582 copies/mL (range 8 - 22,579). 53/58 evaluable patients had undetectable ctHPVDNA within 3 months of completing CRT. 73/89 patients in the surveillance cohort had undetectable ctHPVDNA at all timepoints beyond 3 months post-CRT. 16/89 patients developed a positive ctHPVDNA test result with a median interval from CRT of 16.7 months (range 7.8 − 30.4) and a median value of 75 copies/mL (range 9 − 28,369). 8/16 patients who developed a positive ctHPVDNA test result during surveillance were diagnosed with recurrence (0 local, 1 regional, 7 distant). 8 patients currently have detectable ctHPVDNA (range 23 − 28,369 copies/ml) but have no evidence of recurrence and are being