**Patient Reported Outcomes of NRG Oncology/RTOG 0232: A Phase III Study Comparing Combined External Beam Radiation and Transperineal Interstitial Permanent Brachytherapy with Brachytherapy Alone in Intermediate Risk Prostate Cancer**

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**Purpose/Objective(s):** To assess differences in patient (pt)-reported outcomes (PROs) between combined external beam therapy (EBT) and transperineal interstitial permanent brachytherapy (B) among pts with intermediate risk prostate cancer (PC). The primary endpoint reported that the addition of EBT to B did not result in superior PFS compared to B alone (see Table).

**Materials/Methods:** Men with intermediate risk PC were randomized to either 45 Gy partial pelvis EBT+B or B alone. The Expanded Prostate Index Composite (EPIC) was used to measure change in PROs from baseline to 4 and 24-mos. EPIC assesses 4 PC-specific PRO domains: bowel, urinary (with 2 subscales; incontinence and irritative/obstructive), sexual, and hormonal. Hormonal domain was excluded as concurrent use was exclusionary and prior neoadjuvant use was low (8%). Scoring is on a Likert scale with responses transformed to 0-100, with higher scores indicating better PC-specific PROs. EPIC change (Δ) domain/ subscale scores were calculated as 4 or 24 mo. score - baseline score. To assess treatment differences, effect sizes (ES) ≥ 0.5 standard deviations (SD) were considered clinically significant and t-tests tested for treatment differences > 0.

**Results:** There were 530/579 (92%) eligible pts on study had baseline EPIC: 255 (89%) on EBRT + B arm and 275 (94%) on B arm. There were no significant (sig) differences in baseline characteristics between arms; median age 66, 78% were White and 17% were Black; 89% had GS 7/PSA < 10, 66% were T1 and 96% had Zubrod Performance Status of 0. Grade 3+ toxicities: acute were similar (6%) but late were 13% and 8% for EBT+B and B, respectively. There are no statistically sig differences in any of the baseline mean scores between arms. At 4 mos, mean ± SD of Δ scores for urinary, urinary-irritative, and bowel had sig differences (all p < 0.0001) between arms, all in favor of B alone (ES 0.40, 0.44, 0.31, respectively); none for urinary-incontinence, sexual. At 24 mos, sig differences between arms for urinary, urinary-irritative, bowel, & sexual, all in favor of B alone.

**Conclusion:** Among men with intermediate risk PC in this study, the addition of EBT to B resulted in poorer urinary, bowel, and sexual PROs, with meaningful effect sizes for urinary and bowel, although not meeting the protocol-defined clinically significant level. This study demonstrates that value-based care strongly supports B over EBT + B in this population since B has similar PFS, lower toxicity, better patient reported outcomes and ostensibly less cost compared to the combination.