Hypofractionated post-operative prostate bed radiotherapy does not increase patient-reported toxicity

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A primary endpoint analysis of the NRG Oncology Phase III clinical trial NRG-GU003 comparing hypofractionated post-operative prostate bed radiotherapy (HYPORT) to the conventional post-prostatectomy radiotherapy (COPORT) for men with prostate cancer determined that treatment with HYPORT yielded no increase in patient-reported genitourinary (GU) or gastrointestinal (GI) toxicity for trial participants. However, the trial failed to reject the null hypothesis that dose-escalated radiation therapy (RT) was not superior to conventional RT. These results were presented during the Plenary Session of the American Society for Radiation Oncology's (ASTRO) Annual Meeting in October 2021.

"Radiotherapy is a curative treatment alternative to surgery for men with prostate cancer and short courses are used all the time. Radiotherapy may also be indicated after surgery, but a short course has not been tested. NRG-GU003 is the first trial comparing a short course to a well-established practice standard of 7 weeks. After two years, patients reported no increase in urinary or bowel side effects with the shorter course and its effectiveness was comparable." stated Mark Buyyounouski, MD, of Stanford University and the lead author of the NRG-GU003 manuscript.

NRG-GU003 accrued and randomized 296 men: 144 men were included on the HYPORT treatment arm and 152 men were included on the COPORT treatment arm of the trial. HYPORT dosage was 62.5 Gy to the prostate bed in 25 fractions of 2.5 Gy versus the COPORT dosage of 66.6 Gy in 37 fractions of 1.8 Gy. Researchers used Expanded Prostate Cancer Index Composite (EPIC) scoring to determine inferiority or non-inferiority at 2-years following treatment. Secondary endpoints for the trial included comparing patient-reported GI and GU symptoms at 6, 12, 24 and 60 months from the end of treatment, time to progression, freedom from biochemical failure, local failure, regional failure, salvage therapy, distant metastasis, death from prostate cancer, and overall

survival rates, and adverse events between treatment arms.

"Radiotherapy is a highly effective treatment after surgery if an elevated PSA indicates recurrence of disease. However, a small minority of men receive treatment. We hope these results will better allow patients access to treatment and ultimately reduce the burden of prostate cancer because a safe and shorter treatment is available." added Dr. Buyyounouski.

Compliance with EPIC was 100% at baseline, 83% at the end of radiotherapy, 77% at 6 months, 78% at 12 months, and 73% at 24 months. At the end of radiotherapy, HYPORT and COPORT mean GU change scores were neither clinically significant nor statistically significantly different and remained this way at 6 and 12 months following treatment. HYPORT and COPORT mean GI change scores were both clinically significant and statistically significantly different at the end of radiotherapy (HYPORT mean GI=15.0 vs. COPORT mean GI=6.8 p£ 0.01), however, these differences were resolved by 6 and 12 months following treatment. The 24-month mean GU and GI change scores for HYPORT and COPORT remained neither clinically nor statistically significant (HYPORT mean GU= -5.2 vs. COPORT mean GU= -3.0, p= 0.81; HYPORT mean GI= -2.2 vs. COPORT mean GI= -1.5, p = 0.12). With a median follow-up for censored patients of 2.1 years, there was no difference between HYPORT versus COPORT for biochemical failure defined as a PSA ≥ 0.4 ng/mL followed by a value higher than the first by any amount (2-yr rate, 12% vs 8%, p = 0.29) or local failure (2-yr rate, 0.7% vs 0.8%, p = 0.35).

More information: Conference: www.astro.org/Meetings-and-Edu … /2021/Annual-Meeting

Provided by NRG Oncology

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