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## **Hypofractionated RT can reduce treatment time by one-third with comparable QOL for prostate cancer patients**

*NRG Oncology/RTOG 0415 trial shows similar side effects following conventional and accelerated RT for early stage, low-risk disease*

BOSTON, September 26, 2016 -- For men with early stage, low-risk prostate cancer, treatment with hypofractionated radiation therapy (RT) offers comparable health-related quality of life outcomes in one-third less treatment time than conventional RT, according to research presented today at the 58<sup>th</sup> Annual Meeting of the American Society for Radiation Oncology (ASTRO).

While efficacy results from NRG Oncology/RTOG 0415 were reported previously, this study is the first to report patient-reported outcomes from the trial, which included patients from across the U.S. and Canada. This trial assessed the differences in health-related quality of life (HRQoL), including bowel, urinary, sexual and hormonal side effects, following a conventional or fractionated RT schedule. Compared to conventional (C) RT, hypofractionated (H) RT is delivered in larger doses over a shorter period of time.

“Studies have suggested that higher amounts of radiation over shorter periods of time might be more effective in destroying cancer cells, but the concern has been that stronger doses might also cause quality of life issues such as more diarrhea or decrease in sexual function,” said lead study author Deborah Watkins Bruner, PhD, a professor at the Nell Hodgson Woodruff School of Nursing and a professor of radiation oncology at Emory University School of Medicine in Atlanta.

Patients in the study were randomly assigned to receive either conventional RT, consisting of 73.8 Gy in 41 daily treatments delivered over 8.2 weeks, or hypofractionated RT, consisting of 70 Gy in 28 daily treatments delivered over 5.6 weeks. A total of 962 patients reported HRQoL data, including 478 men

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from the C group and 448 men from the H group. The median patient age was 67 years, and baseline characteristics were similar between the treatment groups.

HRQoL was assessed with the Expanded Prostate Index Composite (EPIC), a comprehensive instrument designed to evaluate patient-reported side effects after prostate cancer treatment. The questionnaire measured side effects in each of EPIC's four domains – bowel, urinary, sexual and hormonal. EPIC assesses prostate cancer-specific HRQoL on a Likert scale with responses transformed to 0-100, where higher scores indicate a better HRQoL. Participant feedback was collected at baseline, six months after treatment began and one year post-treatment, with change scores compared between the C and H groups. A Wilcoxon test was used to assess differences.

At baseline, there were no statistically significant differences between treatment groups in any of the HRQoL domains. Results indicated that, compared to men without prostate cancer, most patients in both groups reported poor baseline EPIC sexual domain scores, with the C group's score averaging 47.5 and the H group's score averaging 44.2. At baseline, the groups reported only slightly lower than average bowel and urinary scores.

Following treatment, patients who received higher doses of RT in fewer sessions (the H group) reported similar HRQoL as the patients who received conventional RT (the C group). There were no differences in change scores for either group on any EPIC domain at six months follow-up. At 12 months follow-up, hypofractionation patients reported a larger decline in the bowel domain compared to those who received conventional RT, with an average from baseline of -3.6 vs. -1.8, respectively, ( $p = 0.0037$ ), but the change was not deemed clinically significant to patients.

"This research shows that hypofractionated radiation therapy offers patients value-based care for their disease. If patients with low-risk prostate cancer choose radiation therapy, they can live equally long and have the same quality of life outcomes with 28 daily treatments, compared to what has been the standard care of 41 daily treatments," said Dr. Bruner. "This reduction of treatment time by almost a third translates into other types of value for patients, such as decreased drive time, lower transportation costs and fewer days off of work."

The abstract, "NRG Oncology/RTOG 0415, Phase III Non-Inferiority Study Comparing 2 Fractionation Schedules in Patients with Low-Risk Prostate Cancer: Prostate Specific Quality of Life Results," will be presented in detail during a scientific session at ASTRO's 58th Annual Meeting at 2:15 p.m. Eastern time on Monday, September 26, 2016. To speak with Dr. Bruner, please contact ASTRO's media relations team on-site at the Boston Convention and Exhibition Center September 25 through 28, by phone at 703-286-1600 or by email at [press@astro.org](mailto:press@astro.org).

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## **ATTRIBUTION TO THE AMERICAN SOCIETY OF RADIATION ONCOLOGY (ASTRO) ANNUAL MEETING REQUESTED IN ALL COVERAGE.**

Full study abstract available on the final page of this release.

### **ABOUT ASTRO'S ANNUAL MEETING**

*ASTRO's 58th Annual Meeting, the nation's premier scientific meeting in radiation oncology, will be held September 25-28, 2016, at the Boston Convention and Exhibition Center in Boston. The 2016 Annual Meeting is expected to attract more than 11,000 attendees from across the globe, including oncologists from all disciplines and members of the entire radiation oncology team. Led by ASTRO president David C. Beyer, MD, FASTRO, the 2016 meeting will feature keynote addresses from Kathleen Sebelius, former U.S. Secretary of Health and Human Services; Thomas James Lynch Jr., MD, Chair and CEO, Massachusetts General Physicians Organization; and Jason Ragona, general manager, SMS and Safety Alliances, Corporate Safety, Security, and Compliance, Delta Air Lines, Inc. The Presidential Symposium, "Prostate Cancer: Defining Value and Delivering It," highlights the meeting's theme of "Enhancing Value, Improving Outcomes" and will feature recent practice-changing studies and current developments in value-based care for prostate cancer. ASTRO's four-day scientific meeting will feature a record number of abstracts, including 368 oral presentations, 1,760 posters and 180 digital posters in more than 50 educational sessions and 20 scientific panels for 20 disease-site tracks. For more information about ASTRO's 58th Annual Meeting, visit [www.astro.org/AnnualMeeting](http://www.astro.org/AnnualMeeting). For press registration and news briefing information for ASTRO's 58th Annual Meeting, visit [www.astro.org/AMPress](http://www.astro.org/AMPress).*

### **ABOUT ASTRO**

*ASTRO is the premier radiation oncology society in the world, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrists and other health care professionals who specialize in treating patients with radiation therapies. As the leading organization in radiation oncology, the Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy. ASTRO publishes three medical journals, International Journal of Radiation Oncology • Biology • Physics ([www.redjournal.org](http://www.redjournal.org)), Practical Radiation Oncology ([www.practicalradonc.org](http://www.practicalradonc.org)) and Advances in Radiation Oncology ([www.advancesradonc.org](http://www.advancesradonc.org)); developed and maintains an extensive patient website, RT Answers ([www.rtanswers.org](http://www.rtanswers.org)); and created the Radiation Oncology Institute ([www.roinstitute.org](http://www.roinstitute.org)), a nonprofit foundation to support research and education efforts around the world that enhance and confirm the critical role of radiation therapy in improving cancer treatment. To learn more about ASTRO, visit [www.astro.org](http://www.astro.org).*

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**NRG Oncology/RTOG 0415, Phase III Non-Inferiority Study Comparing 2 Fractionation Schedules in Patients with Low-Risk Prostate Cancer: Prostate Specific Quality of Life Results**

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**Purpose/Objective(s):** To assess differences in health related quality of life (HRQoL) between hypofractionated (H) and conventional (C) schedule radiation therapy (RT) in men with low-risk prostate cancer.

**Materials/Methods:** Eligibility included: stage T1-2a, Gleason  $\leq 6$ , PSA  $< 10$ , randomized to a C schedule (3D/IMRT 73.8 Gy in 41 fractions [fx] over 8.2 wks) or a H schedule (3D/IMRT 70 Gy in 28 fxs over 5.6 wks). HRQoL was assessed with the Expanded Prostate Index Composite (EPIC) at baseline, 6 and 12 mos. EPIC assesses prostate cancer-specific HRQoL on a Likert scale with responses transformed to 0-100 (higher scores indicating better HRQoL; 0.5 SD change indicating clinical significance). EPIC has 4 domains: bowel, urinary, sexual, and hormonal. Each domain requires at least 80% of items to be completed. Change scores, calculated as follow-up – baseline, at 6 and 12 mos were compared between arms. Wilcoxon test was used to assess differences. A significance level of 0.0125 to adjust for multiple comparisons with respect to the 4 domain scores was used for an overall two-sided type I error of 0.05.

**Results:** Of 1092 pts analyzable for the primary endpoint, 962 consented to HRQoL (478 on 73.8 Gy arm; 448 on 70 Gy arm). Baseline characteristics were similar between treatment arms. Median age = 67 yrs; HRQoL compliance was 89.4% at baseline, 72.7% at 6 mos, and 65.9% at 1 yr. Compared to men without cancer<sup>1</sup>, most pts reported poor baseline EPIC sexual domain scores in both H and C arms, median 44.2 and 47.5, and only slightly lower than average bowel and urinary scores. No statistically significant differences with regard to any of the HRQoL baseline domains were measured between treatment arms. There were no differences in change score between arms of any domain scores at 6 mos. At 12 mos, those on the 70 Gy arm experienced a larger decline as compared to those on the 73.8 Gy arm in the bowel domain (median 12 mo. scores 91.1 vs 94.6; median change scores from baseline -3.6 vs. -1.8, respectively,  $p=0.0037$ ), but not clinically significant.

**Conclusion:** Compared to a study of EPIC norms<sup>1</sup> in men without cancer, baseline scores for bowel and urinary domains were about 5-6 points lower and sexual function was 15 points lower than norms. Men receiving either H or C fractionation schedules demonstrated 12 mo. bowel, urinary, and better sexual HRQoL comparable to the recent large European H study.<sup>2</sup> EPIC scores exhibited only a small magnitude of decline at 1 yr follow-up from baseline. As compared with C fx, pts treated with H demonstrated a small statistically, but not clinically significant, larger decline in bowel HRQoL at 1 yr, thus late toxicity is comparable between arms, supporting value based care with H.

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