

Embargoed until 7:45 am ET, Monday, September 26, 2016

Contact: Liz Gardner
703-286-1600
liz.gardner@astro.org

Nancy Mayes
Mayes Communications
703-772-2510
nancy@mayescommunications.com

SBRT offers prostate cancer patients high cancer control and low toxicity in fewer treatments

Multi-institutional study finds five-year progression-free survival in 97 percent of patients and severe side effects in fewer than 2 percent

BOSTON, September 26, 2016 -- High dose stereotactic body radiotherapy (SBRT) for men newly-diagnosed with low- or intermediate-risk prostate cancer results in shorter treatment times, low severe toxicity and excellent cancer control rates, according to research presented today at the 58th Annual Meeting of the American Society for Radiation Oncology (ASTRO). The study is the first large, multi-institutional study of SBRT in prostate cancer with long-term follow-up.

Although prostate tumors generally respond well to radiation therapy (RT), the possibility of radiation exposure to healthy tissue in the genitourinary (GU) and gastrointestinal (GI) systems can be of concern. SBRT is an advanced technique that precisely targets high doses of RT to the tumor in a small number fractions, simultaneously avoiding surrounding tissue and reducing toxicity to non-cancerous cells. The technique has become the standard of care for many non-surgical lung cancer patients, as it limits exposure to the heart and surrounding lungs. When treating tumors in the prostate, SBRT avoids the adjacent bladder, sex organs and rectum.

“Single-institution studies on the use of SBRT as the primary treatment for prostate cancer have illuminated the treatment as a cost-effective and faster alternative to IMRT,” said Robert Meier, MD, lead author of the study and a radiation oncologist at Swedish Medical Center in Seattle. “Our study is the first to contribute multi-center data that support the use of SBRT as front-line therapy for men with prostate cancer.”

A total of 309 men with newly diagnosed prostate cancer were enrolled in the trial at 21 community,

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

251 18TH STREET SOUTH • 8TH FLOOR • ARLINGTON, VA 22202 • PHONE: 703-502-1550 • FAX: 703-502-7852 • www.astro.org
ASTRO Press Office: press@astro.org • PHONE: 703-286-1600 • FAX: 703-286-1601

regional and academic hospitals across the U.S. Eligible patients had either low-risk disease (CS T1-T2a, Gleason 6, PSA < 10) ($n = 172$) or intermediate-risk disease (CS T1c-T2b with either Gleason 7 and PSA < 10, or Gleason 6 and PSA 10-20). All of the men received SBRT via a non-isocentric robotic platform, with an RT dose to the prostate of 40 Gy administered in five treatment sessions of 8 Gy each. Intermediate risk patients received a dose of 36.25 Gy to the seminal vesicles. Concurrent and adjuvant androgen ablation therapy were prohibited among study participants.

Primary outcomes included GU and GI toxicities and relapse-free survival (RFS). Researchers measured toxicity using the National Cancer Institute's Common Terminology Criteria for Adverse Events (CTCAE) version 3.0. Biochemical failure was assessed using the ASTRO-consensus and the nadir+2 definitions. Overall survival (OS) was measured as a secondary outcome for the study. Actuarial OS and RFS were calculated with the Kaplan-Meier statistical method. Median follow-up was 61 months.

At five years following SBRT, 97 percent of patients were free from prostate cancer progression. In low-risk patients, the cancer control rates was superior to historical controls. Specifically in the low-risk group, the five-year RFS rate was 97.3 percent, which is superior to the 93 percent historical comparison DFS control rate ($p = 0.014$). Actuarial five-year OS was 95.6 percent for the entire cohort. Actuarial five-year nadir+2 RFS was 97.1 percent for all patients, representing 97.3 percent of low-risk and 97.1 of intermediate-risk patients. Actuarial five-year ASTRO RFS was 92.3 percent and 91.3 percent for low- and intermediate-risk groups, respectively.

Fewer than two percent of all patients experienced serious side effects in the five years following SBRT. Five grade three GU side effects were reported in four of the 309 study participants. There were no reported grade four or five toxicities nor any grade three GI toxicities. Between half and two-thirds of patients experienced less serious side effects, with rates of 53 and 59 percent for grade one GU and GI toxicities and rates of 35 and 10 percent for grade two GU and GI toxicities, respectively. These side effects were usually temporary.

"Our results illustrate how advanced technology has radically improved our ability to target cancer," said Dr. Meier. "After following patients for more than five years, we found that serious side effects from a brief course of SBRT were uncommon and that cancer control rates were very favorable compared to historical data. Our trial confirms that SBRT may be preferable to other treatment approaches for newly-diagnosed cases of prostate cancer, including more aggressive disease."

The abstract, "Five-Year Outcomes from a Multi-Center Trial of Stereotactic Body Radiotherapy for Low- and Intermediate-Risk Prostate Cancer," will be presented in detail during a scientific session at ASTRO's 58th Annual Meeting at 7:45 a.m. Eastern time on Monday, September 26, 2016. To speak with Dr.

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

251 18TH STREET SOUTH • 8TH FLOOR • ARLINGTON, VA 22202 • PHONE: 703-502-1550 • FAX: 703-502-7852 • www.astro.org
ASTRO Press Office: press@astro.org • PHONE: 703-286-1600 • FAX: 703-286-1601

Meier, 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.

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

This news release contains updated data from the study author(s). 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 Ragogna, 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. For press registration and news briefing information for ASTRO's 58th Annual Meeting, visit 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), Practical Radiation Oncology (www.practicalradonc.org) and Advances in Radiation Oncology (www.advancesradonc.org); developed and maintains an extensive patient website, RT Answers (www.rtanswers.org); and created the Radiation Oncology Institute (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.

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

251 18TH STREET SOUTH • 8TH FLOOR • ARLINGTON, VA 22202 • PHONE: 703-502-1550 • FAX: 703-502-7852 • www.astro.org
ASTRO Press Office: press@astro.org • PHONE: 703-286-1600 • FAX: 703-286-1601

Abstract ID: 74

ASTRO News Briefing: Advances in Prostate Cancer Care, Tuesday, September 27, 2016, 8:00 a.m. - 9:00 a.m. ET

Scientific Session: Monday, September 26, 2016, 7:45 a.m. - 9:15 a.m. ET

Five-Year Outcomes from a Multi-Center Trial of Stereotactic Body Radiotherapy for Low- and Intermediate-Risk Prostate Cancer

R. Meier¹, A. Beckman², G. Henning³, N. Mohideen⁴, S. A. Woodhouse⁵, C. Cotrutz¹, and I. D. Kaplan⁶; ¹Swedish Cancer Institute, Seattle, WA, ²Central Baptist Hospital, Lexington, KY, ³Huron River Radiation Oncology, Brighton, MI, ⁴Northwest Community Hospital, Arlington Heights, IL, United States, ⁵Community Cancer Center, Normal, IL, ⁶Beth Israel Deaconess Medical Center, Boston, MA

Purpose/Objective(s): Single-institution studies suggest stereotactic body radiotherapy (SBRT) is a cost-effective alternative to IMRT as primary therapy for prostate cancer. We hypothesized that dose-escalated SBRT could be safely administered across multiple institutions, with grade 3+ toxicities not exceeding 10%. With median follow up greater than five years, we report toxicity, survival and relapse-free survival (RFS) outcomes.

Materials/Methods: After completing rigorous credentialing requirements, 21 community, regional, and academic hospitals enrolled 309 evaluable patients with biopsy-proven adenocarcinoma of the prostate, confirmed by central pathologic review: 172 low-risk (CS T1-T2a, Gleason 6, PSA < 10 ng/mL) and 137 intermediate-risk (CS T1c-T2b with either Gleason=7 and PSA < 10 ng/mL, or Gleason 6 and PSA between 10 and 20 ng/mL). All patients were treated with a non-isocentric robotic SBRT platform using real-time tracking of implanted fiducials. The prostate was prescribed 40 Gy in 5 fractions of 8 Gy and seminal vesicles received 36.25 Gy. Normal tissues were rigidly constrained (rectal V36 Gy <1 cc; bladder V37 Gy <5-10 cc). No patient had concomitant or adjuvant androgen ablation therapy. Toxicities were assessed using CTCAE v3 criteria. Patient-reported quality of life outcomes were recorded and reported elsewhere. Biochemical failure was assessed using the ASTRO consensus and the nadir+2 definitions. Actuarial survival outcomes were calculated using Kaplan Meier methods. The study populations yielded a 90% power of identifying excessive (>10%) rates of grade 3+ GU or GI toxicities at the one-sided 5% significance level.

Results: Median follow-up was 61 months. Five grade 3+ toxicities (1.6%) were reported, far below the 10% rate deemed excessive. There were no grade 4 or 5 toxicities. All reported grade 3 toxicities were GU; these occurred between 11 and 51 months after treatment. Toxicities rates are summarized below. Five patients (1.6%) developed urinary retention which required a temporary catheter placement. Seven patients were diagnosed with bladder cancers between 21 and 50 months after treatment. For the entire population, actuarial 5-year overall survival was 95.6%. Actuarial 5-year nadir+2 RFS was 97.1% for all patients, and was 97.3% and 97.1% for the low- and intermediate-risk groups, respectively. Actuarial 5-year ASTRO RFS was 92.3% and 91.3% for these respective risk groups.

Conclusion: With appropriate treatment delivery and constraints, dose-escalated prostate SBRT can be safely administered across multiple institutions. Toxicity rates and RFS rates compare favorably to other radiotherapies. SBRT appears to be a suitable option for low- and intermediate-risk prostate cancer. ClinicalTrials.gov identifier NCT00643994

	GU Toxicity				GI Toxicity		
	Gr1	Gr2	Gr3	Gr4+	Gr1	Gr2	Gr3+
Any time	165 (53%)	108 (35%)	5 (2%)	0	183 (59%)	31 (10%)	0
< 3 mos	182 (59%)	79 (26%)	0	0	169 (55%)	25 (8%)	0
> 3 mos	87 (28%)	38 (12%)	5 (2%)	0	38 (12%)	6 (2%)	0

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

251 18TH STREET SOUTH • 8TH FLOOR • ARLINGTON, VA 22202 • PHONE: 703-502-1550 • FAX: 703-502-7852 • www.astro.org

ASTRO Press Office: press@astro.org • PHONE: 703-286-1600 • FAX: 703-286-1601