

## News Release

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## External beam radiation therapy for early-stage breast cancer does not increase mortality risks due to cardiac conditions or secondary cancers

Atlanta, September 24, 2013 — Early-stage breast cancer patients who receive external beam therapy (XRT) are not at higher risk for serious long-term side effects in the chest area, including increase in deaths from cardiac disease and secondary malignancies, according to research presented today at the American Society for Radiation Oncology's (ASTRO's) 55th Annual Meeting.

The study utilized patient information from the National Cancer Institute's Surveillance, Epidemiology and End Results (SEER) database. It evaluated women identified as having primary Stage T1aN0 breast cancer (tumor of 5mm or less that has not spread to the lymph nodes), who received surgery, with or without post-operative radiation therapy, between 1990 and 1997. The analysis was done to determine if XRT was associated with increased mortality due to breast cancer, secondary cancer in the chest area or cardiac conditions for these patients; only patients with breast cancer (BC) identified as the first malignancy were included. The women had a median age of 55-59 and were divided into two groups: 2,397 who received XRT after surgery, and 2,988 who did not receive XRT after surgery.

Cause of death (COD) codes were used to identify cardiac mortality, breast cancer mortality, and deaths from secondary chest cancers in order to assess overall survival (OS), breast cancer survival (BCS), second-tumor specific survival and cardiac-cause specific survival (CCS), and then compared between the XRT and non-XRT groups. The incidence of mortality was compared between the XRT and non-XRT groups utilizing the Chi-Square test; and, the relative risk (RR) and associated 95 percent confidence interval (CI) were calculated. Kaplan-Meier survival analysis and log-rank test were performed to assess OS, BCS, second-tumor specific survival and CCS.

At 10 years post-treatment, OS rates were 91.6 percent for the XRT patients and 87 percent for the non-XRT group; BCS rates were 97 percent for the XRT patients and 95.7 percent for the non-XRT group; and CCS was 96.7 percent for the XRT patients and 92.7 percent for the non-XRT group.

Analysis of the data further demonstrates that, with a median follow up of 14 years, there was no statistically significant difference in deaths from subsequent non-breast cancers in the chest area, the majority of which were lung cancers. The number of deaths from cardiac causes was not significantly higher for those patients treated with XRT for left-sided breast cancer, compared to those with right-sided breast cancer among the patient sample and time period reviewed. More women from the non-XRT group died from all causes, including cardiac causes, suggesting that those patients had worse general health conditions than the women who received radiation therapy.

"Breast conserving therapy, consisting of lumpectomy and XRT, has been an excellent approach to early breast cancer treatment, offering equivalent disease control and better cosmetic results compared to mastectomy as demonstrated by multiple randomized controlled trials in the past," said Jason Ye, MD, the study's presenting author and a second-year resident in radiation oncology at Weill Cornell Medical College in New York City. "Our study's results suggest that serious long-term side effects of radiation therapy, such as increase in deaths from cardiac disease and secondary malignancies, are rare. Radiation therapy is an integral part of early stage breast cancer treatment for those who choose to have a lumpectomy instead of a mastectomy, with its benefits likely far outweighing the potential risks in majority of the cases. The field of radiation oncology is rapidly changing, with new technology constantly being introduced that may reduce

these risks further. Continued long term follow up and additional studies are needed to monitor for potential long term side effects."

The abstract, "Breast Cancer (BC), Second Cancer, and Cardiac Mortality in Stage T1aN0 BC Patients with or without External Beam Radiation Therapy (XRT): NCI SEER Study," will be presented in detail during a scientific session at ASTRO's 55th Annual Meeting at 1:00 p.m. Eastern time on Tuesday, September 24, 2013. To speak with Dr. Ye, contact Michelle Kirkwood on September 22-25, 2013, in the ASTRO Press Office at the Georgia World Congress Center in Atlanta at 404-222-5303 or 404-222-5304, or email <a href="michellek@astro.org">michellek@astro.org</a>.

ASTRO's 55th Annual Meeting, held in Atlanta, September 22-25, 2013, is the premier scientific meeting in radiation oncology and brings together more than 11,000 attendees including oncologists from all disciplines, medical physicists, dosimetrists, radiation therapists, radiation oncology nurses and nurse practitioners, biologists, physician assistants, practice administrators, industry representatives and other health care professionals from around the world. The theme of the 2013 meeting is "Patients: Hope • Guide • Heal" and focuses on patient-centered care and the importance of the physician's role in improving patient-reported outcomes and the quality and safety of patient care. The four-day scientific meeting includes presentation of four plenary papers, 363 oral presentations, 1,460 posters and 144 digital posters in 70 educational sessions and scientific panels for 19 disease sites/tracks. Keynote and featured speakers include: William B. Munier, director of the Center for Quality Improvement and Patient Safety at the Agency for Healthcare Research and Quality; Darrell G. Kirch, MD, president and CEO of the Association of American Medical Colleges; James Cosgrove, PhD, director of the U.S. Government Accountability Office; Otis W. Brawley, MD, chief medical officer of the American Cancer Society; and Peter Friedl, MD, PhD, of St. Radboud University Nijmegen Medical Centre at the University of Nijmegen and MD Anderson Cancer Center.

## **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 that 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 two medical journals, International Journal of Radiation Oncology • Biology • Physics (www.redjournal.org) and Practical Radiation Oncology (www.practicalradonc.org); developed and maintains an extensive patient website, www.rtanswers.org; and created the Radiation Oncology Institute (www.roinstitute.org), a non-profit 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.

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## 2013 American Society for Radiation Oncology (ASTRO) 55<sup>th</sup> Annual Meeting News Briefing, Tuesday, September 24, 2013, 8:15 a.m. Eastern time

Scientific Session: Tuesday, September 24, 2013, 1:00 – 2:30 p.m. ET, Georgia World Congress Center

Publishing Title: Breast Cancer (BC), Second Cancer, and Cardiac Mortality in Stage T1aN0 BC Patients with or without External Beam Radiation Therapy (XRT): NCI SEER Study

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**Purpose/Objective(s):** While studies have shown breast conservation treatment (BCT) incorporating lumpectomy and XRT to be equivalent to mastectomy in overall survival (OS), and BC specific survival (BCS), the potential adverse late effects of XRT to the chest area must be considered. We examined the cardiac mortality and second cancer mortality and the possible association with XRT in patients with the best prognosis BC.

Materials/Methods: All women who had breast conserving surgery or mastectomy with or without adjuvant XRT for Stage T1aN0 breast malignancy in 1990-1997 were identified in the SEER database. Only BC identified as first malignancy was included. Cause of death (COD) codes were used to identify cardiac mortality (cardiac disease and athrosclerosis), BC mortality, and deaths from second cancers in the chest area. The incidence of mortality was compared between the XRT and no-XRT groups using Chi-square test, and the relative risk (RR) and associated 95% confidence interval (CI) were calculated. Kaplan-Meier survival analysis and log-rank test were performed to assess OS, BCS, second tumor specific survival, and cardiac cause specific survival (CCS).

**Results:** A total of 2397 T1aN0 patients who received XRT after BC surgery and 2988 who did not were included in this study. The median age was similar (55-59 years) for both groups. The median follow up periods were also similar (XRT: 169 mo, no-XRT: 171 mo). Compared to the no-XRT group, XRT group was associated with lower overall mortality (p<0.001, RR 0.69, CI 0.61-0.78), BC mortality (p=0.02, RR 0.75, CI 0.59-0.95), and cardiac mortality (p<0.001, RR 0.53, CI 0.44-0.64). The 10-year OS for XRT and no-XRT groups were 91.6%mo and 87.0%, respectively (p<0.001). The 10-year BCS in the XRT and no- XRT groups was 97.0% and 95.7%, respectively (P=0.01). The 10-year CCS in the XRT and no-XRT groups were 96.7% and 92.7%, respectively (p<0.001). In the XRT group, having left sided BC did not increase the incidence of cardiac mortality compared to right sided BC. There were no statistically significant incidences in mortality due to subsequent lung, esophageal, soft tissue, lymphoma, and leukemic cancers. The most common second cancer mortality included 94 (2%) lung, 24 (0.4%) lymphoma, 21 (0.4%) leukemia, 3 (0.06%) soft tissue including heart, and 2 (0.04%) esophagus.

**Conclusions:** This review of the SEER data suggests that XRT is not associated with increased mortality due to BC, secondary cancer in the chest area, or cardiac conditions, and supports the continued use of BCT in early stage BC.

Author Disclosure Block: J.C. Ye: None. W. Yan: None. P.J. Christos: None. D. Nori: None. K.C. Chao: None. A. Ravi: None.