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Contact: Liz Gardner  
703-286-1600  
[liz.gardner@astro.org](mailto:liz.gardner@astro.org)

Nancy Mayes  
Mayes Communications  
703-772-2510  
[nancy@mayescommunications.com](mailto:nancy@mayescommunications.com)

## **Radiation boost reduces local tumor recurrence for DCIS patients following WBRT**

*Pooled data from ten universities finds added benefit from radiation boost among patients with negative margins following breast-conserving surgery*

BOSTON, September 27, 2016 -- A supplemental “boost” of radiation improves local control and provides an incremental benefit in decreasing breast cancer recurrence for patients with Ductal Carcinoma In Situ (DCIS) who receive whole breast radiation therapy radiation (WBRT) following lumpectomy, according to research presented today at the 58<sup>th</sup> Annual Meeting of the American Society for Radiation Oncology (ASTRO). Researchers concluded that use of a radiation boost should be considered in DCIS patients who have life expectancies of 10 or more years following breast-conserving surgery and WBRT.

DCIS patients undergoing breast conservation therapy typically receive a lumpectomy to remove the tumor, followed by WBRT to eliminate any residual cancerous cells within the breast. Following WBRT, many patient receive an additional boost of radiation of four-to-eight fractions to the surgical bed, which is the region at the highest risk for recurrence. While multiple clinical trials have demonstrated a modest but statistically significant reduction in ipsilateral breast tumor recurrence (IBTR) from a radiation boost after WBRT for *invasive* breast cancer, there are, to date, no published phase III studies examining radiation boost for DCIS.

Ten academic institutions from the United States, Canada and France provided de-identified patient level data for 4,131 cases of DCIS, collaborating to analyze the benefit of the DCIS boost by assembling the largest cohort of patients with DCIS treated with or without boost to date. Eligible patients included those with pure DCIS (i.e., no micro-invasion) who received WBRT with or without radiation boost and reached a minimum of five years follow-up. Eligible patients received either electron or photo radiation boost, and

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the median boost dose was 14 Gy. Records documenting patients receiving a brachytherapy boost, those having an unknown boost status or those receiving partial breast radiation were not included in the analyses. Among the 4,131 cases included in this analysis, 2,661 patients received a radiation boost, and 1,470 did not. Use of radiation boost was more common for patients with positive margins following breast-conserving surgery, those with unknown estrogen receptor (ER) status and individuals with the presence of necrosis documented on their pathology report. Median follow-up for all study participants was nine years.

DCIS patients who received a radiation boost following WBRT experienced a reduction in local recurrence. The IBTR-free survival for boost vs. no boost, respectively, was 97.1 percent vs. 96.3 percent at five years, 94.1 vs. 92.5 percent at ten years, and 91.6 vs. 88.0 percent at 15 years following treatment, with these differences achieving statistical significance ( $p = 0.013$ ).

“Many radiation oncologists routinely deliver a boost after WBRT for DCIS, anticipating a similar benefit to our experience with invasive cancers. But we haven’t had consistent data to demonstrate this benefit in DCIS. Our study has demonstrated that the use of a radiation boost provides an albeit small but significant long-term benefit in reducing breast tumor recurrence for DCIS patients and supports the consideration of a DCIS boost in patients undergoing WBRT who have life expectancies of 10 or more years,” said Meena Savur Moran, MD, lead study author, professor of therapeutic radiology at Yale School of Medicine and director of the Radiation Oncology Breast Program at Smilow Cancer Hospital at Yale New Haven.

The benefit in reducing in-breast recurrence was demonstrated across all DCIS age subgroups. Furthermore, treatment with the DCIS boost was an independent predictor for decreasing IBTR on multivariate analyses controlling for other patient and disease characteristics (i.e., grade, necrosis, margin status, patient age, tumor size and use of tamoxifen). On subset analysis, though the boost did not convey a statistically significant benefit in the subset of patients with positive margins ( $p = 0.99$ ), it did independently predict for reducing IBTR in all DCIS age groups with negative margins (all  $p < 0.02$ ). Moran explained, however, that only four percent of study participants comprised the subset of patients with positive margins, so it is highly likely the positive margin subset was underpowered to show a statistically significant benefit.

“Our findings suggest that adding several additional fractions of radiation directed to the lumpectomy cavity after whole breast radiation for DCIS provides an incremental benefit in decreasing local relapse, similar in magnitude to the four percent at 20 years benefit of the boost for invasive cancers,” said Dr. Moran. “While these small numbers may not *seem* substantial, the invasive boost data

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have highlighted to us the clinical importance that small decreases in local relapse provide for patients. Ultimately, these small decreases in IBTR resulted in reduced the number of mastectomies for recurrence by approximately 40 percent in patients who had received a boost, compared with no-boost.”

The abstract, “Radiation Boost for Ductal Carcinoma In Situ After Whole Breast Radiation Therapy (WBRT) Improves Local Control: Analysis from Ten Pooled Academic Institutions,” will be presented in detail during a scientific session at ASTRO’s 58th Annual Meeting at 1:30 p.m. Eastern time on Tuesday, September 27, 2016. To speak with Dr. Moran, 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).

**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 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](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*

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*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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## **Radiation Boost for Ductal Carcinoma In Situ After Whole Breast Radiation Therapy (WBRT) Improves Local Control: Analysis from Ten Pooled Academic Institutions**

M. S. Moran<sup>1</sup>, Y. Zhao<sup>1</sup>, S. Ma<sup>1</sup>, Y. M. Kirova<sup>2</sup>, A. Fourquet<sup>3</sup>, P. Y. Chen<sup>4</sup>, K. E. Hoffman<sup>5</sup>, K. K. Hunt<sup>6</sup>, J. S. Wong<sup>7</sup>, L. M. Halasz<sup>8</sup>, G. M. Freedman<sup>9</sup>, R. G. Prosnitz<sup>10</sup>, M. Yassa<sup>11</sup>, D. H. A. Nguyen<sup>11</sup>, T. Hijal<sup>12</sup>, B. G. Haffty<sup>13</sup>, E. S. Wai<sup>14</sup>, and P. Truong<sup>15</sup>; <sup>1</sup>Yale University, New Haven, CT, <sup>2</sup>Institut Curie, Paris, France, <sup>3</sup>Institut Curie, Paris 75005, France, <sup>4</sup>Beaumont Health System, Royal Oak, MI, <sup>5</sup>The University of Texas MD Anderson Cancer Center, Division of Radiation Oncology, Houston, TX, <sup>6</sup>MD Anderson Cancer Center, Houston, TX, <sup>7</sup>Brigham and Women's Hospital, Boston, MA, <sup>8</sup>University of Washington, Department of Radiation Oncology, Seattle, WA, <sup>9</sup>University of Pennsylvania, Department of Radiation Oncology, Philadelphia, PA, <sup>10</sup>Allentown Radiation Oncology Associates, Allentown, PA, United States, <sup>11</sup>Maisonneuve-Rosemont Hospital, Montreal, QC, Canada, <sup>12</sup>McGill University Health Centre, Montreal, QC, Canada, <sup>13</sup>Rutgers Cancer Institute of New Jersey, New Brunswick, NJ, <sup>14</sup>BC Cancer Agency, Surrey, BC, Canada, <sup>15</sup>British Columbia Cancer Agency, Victoria, BC, Canada

**Purpose/Objective(s):** The current rationale for using a radiation boost after whole breast radiation (WBRT) for DCIS is largely extrapolated from phase III *invasive* cancer trials that have demonstrated its benefit in decreasing ipsilateral breast tumor recurrence (IBTR). Demonstrating this benefit for DCIS specifically has been a challenge due to its long natural history & limited IBTR events after WBRT. Hence, current data are limited to conflicting series restricted in size, IBTR and/or follow up. In this study, a DCIS cohort was assembled based on an *a priori* power analysis which estimated the sample size needed to detect the anticipated benefit from the boost. This cohort was analyzed to assess the independent effects of the boost for in-situ disease.

**Materials/Methods:** IRB approvals & data sharing agreements were obtained from the 10 participating academic institutions across USA, Canada & France. De-identified patient level data were uniformly re-coded at the host institution and underwent 1<sup>o</sup> and 2<sup>o</sup> review prior to inclusion for analysis. Patients with pure DCIS treated with WBRT +/- electron or photon boost and 5 years minimum follow-up were eligible. DCIS cases with micro-invasion, brachytherapy boost, or unknown boost status were excluded. Sample size calculations (ratio of 2:1,  $\alpha=0.05$ , power=80%) estimated 2,982 patients (1,988 boost; 994 no boost) would be needed to detect a 3% or greater benefit (ie- 10 yrs IBTR: 10% no boost vs. 7% boost)

**Results:** Of 4,376 DCIS cases collected, the cohort eligible for analysis consisted of 4,131 patients ( $N_{\text{boost}} = 2,661$ ,  $N_{\text{no boost}}=1,470$ ). For the entire cohort, median f/u was 9 yrs; median age was 56 yrs; median boost dose was 14 Gy. Patients with +margins, unknown ER status and +necrosis were more likely to have received a boost (all  $p<0.05$ ). The IBTR-free survival was 97.1% vs 96.3% ( $p=0.18$ ), 94.1% vs 92.5% ( $p=0.12$ ) & 91.6% vs 88% ( $p=0.03$ ) at 5, 10, & 15 years for boost vs no boost, respectively. Of the 4,131 patients, the overall IBTR was significantly less in those receiving boost compared with no boost ( $p=0.013$ ). Subset analysis failed to demonstrate any benefit of the boost when a +margin was reported ( $p=0.99$ ). The multivariate analysis incorporated grade, necrosis, ER & margin status, age, size & tamoxifen-use demonstrated that the boost remained an independent predictor for decreasing IBTR ( $p=0.013$ ), significant in all patients with negative margins irrespective of age group (all  $p<0.02$ ).

**Conclusion:** In the absence of PIII data, this study represents the largest dataset with longest follow-up supporting the use of a radiation boost for DCIS. Our findings demonstrate that the boost provides a small but statistically significant benefit of similar magnitude to that seen in invasive cancers. While the use of a boost is unlikely to overcome the detrimental effects of a +margin, it should be considered for margin-negative DCIS patients undergoing WBRT who have life expectancies >10-15 years, to provide an additional incremental benefit in decreasing IBTR.

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