Accelerated partial breast irradiation (APBI) using multicatheter brachytherapy after breast conserving surgery is as effective as whole breast irradiation (WBI) for low-risk patients

_**Long-term, five-year follow-up demonstrates equivalent local control, disease-free and overall survival rates**_

San Antonio, October 19, 2015—For some early stage breast cancer patients, accelerated partial breast irradiation (APBI) using multicatheter brachytherapy following breast conserving surgery may be an excellent treatment option, as it has now been proven to be as effective as the current standard treatment – whole breast irradiation (WBI) – in local control, disease-free and overall survival rates, according to research presented today at the American Society for Radiation Oncology’s (ASTRO’s) 57th Annual Meeting.

Breast cancer patients often receive radiation therapy (RT) after breast-conserving surgery to help lower the chance that the cancer will recur or metastasize in the nearby lymph nodes. WBI using external beam radiation is a longstanding standard RT for breast cancer patients, during which the entire breast and often the surrounding chest area receives radiation for several weeks, followed by an extra boost of radiation to the area where the cancer was removed. Many women in the U.S. who are eligible for breast conserving surgery still choose to undergo mastectomy in the hopes that it will...
make subsequent WBI unnecessary, due largely to the long-duration of WBI and/or because of fears concerning the potential side effects of radiation to surrounding organs.

APBI with multicatheter brachytherapy is a technique that delivers the effective radiation dose directly to the tissue at risk, which reduces the administration period and limits adverse side effects, particularly the burden on surrounding tissues of the heart, lungs, and skin. The compact timing of APBI therapy is particularly significant for elderly patients, working women, and those who live a significant distance from a radiation treatment facility.

This phase III study was conducted from April 2004 and July 2009, across 16 centers throughout Europe. The trial compared the results of 1,184 patients aged 40 or older with early stage breast cancer (0, I and IIA) who received breast conserving surgery and were then randomly assigned to receive either conventional treatment, consisting of 50 Gy WBI with tumor bed boost of 10 Gy for approximately seven weeks, or APBI using interstitial multicatheter brachytherapy for five days. Median follow-up of patients was 6.6 years, and baseline factors were evenly distributed across arms. The primary endpoint was local recurrence. Secondary endpoints were incidence and severity of acute and late side effects, cosmesis, cumulative incidence of lymph node metastases and distant metastasis, overall survival (OS), and disease-free survival (DFS).

Long-term follow-up results demonstrate that for the selected low-risk patients, APBI yielded equivalent local control, as well as DFS and OS, compared to conventional WBI. In the APBI group, five-year local recurrence rates were 1.4 percent, five-year DFS was 95 percent, and five-year OS rates were 97.3 percent. By contrast, the WBI group showed five-year local recurrence rates of 0.9 percent, five-year disease-free survival of 94.5 percent, and five-year overall survival rates of 95.6 percent. The equivalence of local recurrence rates was evident in all age groups and in all tumor types, independent of additional drug therapy (e.g. chemotherapy, antihormonal therapy).

“The results of our study show that, at present, multicatheter brachytherapy is an attractive and viable APBI treatment option for low-risk breast cancer patients after breast conserving surgery,” said Vratislav Strnad, MD, PhD, lead author of the study and professor in the department of radiation oncology at University Hospital Erlangen, Germany. “The results were not totally
surprising, because as we were preparing our phase III trial the first long-term results of several smaller phase II trials were published showing low recurrence rates after breast-conserving treatment and APBI in comparison to WBI. What is surprising, however, is how clear the results are. Our favorable results are in contrast with the disappointing and controversial results reported from other studies that used other APBI techniques, such as intraoperative and external beam radiation therapy.”

Prior recommendations have indicated that patients should be at least 50- (ESTRO) or 60-years-old (ASTRO) before receiving APBI. However, this study demonstrates excellent results in all participant age groups, including those aged 40 and older. Further research and analyses will need to be conducted to determine recurrence rates among different age subgroups at follow-up beyond five years.

The abstract, “Accelerated partial breast irradiation using sole interstitial multicatheter brachytherapy versus whole breast irradiation for early breast cancer: 5-year results of a randomized phase III trial – Part I: Local control and survival results” will be presented in detail during a scientific session at ASTRO’s 57th Annual Meeting at 2:15 p.m. Central time on Monday, October 19, 2015. To speak with Dr. Strnad, please call Nancy Mayes in ASTRO’s Press Office at the Henry B. González Convention Center in San Antonio on October 18 – 21, 2015 at 210-258-8104 or 210-258-8105, or email press@astro.org.

ASTRO’s 57th Annual Meeting, being held at the Henry B. González Convention Center in San Antonio, October 18-21, 2015, is the nation’s premier scientific meeting in radiation oncology. The 2015 Annual Meeting is expected to attract 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. Led by ASTRO President Bruce D. Minsky, MD, FASTRO, a radiation oncologist specializing in gastrointestinal cancers, Professor of Radiation Oncology, and the Frank T. McGraw Memorial Chair at The University of Texas MD Anderson Cancer Center, Houston, the theme of the 2015 Meeting is “Technology Meets Patient
Care.” Dr. Minsky’s Presidential Symposium, “Multidisciplinary Management of Esophageal and Rectal Cancers,” will feature Leonard L. Gunderson, MD, MS, FASTRO, and Joel E. Tepper, MD, FASTRO, to highlight imaging, staging, genomics and data mining approaches, as well as the latest advances in esophageal and colorectal cancer treatment. ASTRO’s four-day scientific meeting includes presentation of more than 2,100 abstracts: five plenary papers, 351 oral presentations, 1,609 posters and 171 digital posters in more than 53 educational sessions and 26 scientific panels for 20 disease-site tracks. Three keynote speakers will address a range of topics including cancer biology in radiation oncology, the essential roles of a physician, and patient safety: Arul Chinnaian, MD, PhD, Professor and Director, Michigan Center for Translational Pathology; Francisco G. Cigarroa, MD, Past President and Chancellor, University of Texas; and Gerald B. Hickson, MD, Senior Vice President and Assistant Vice Chancellor, Vanderbilt University Medical 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 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, 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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LBA7 Accelerated partial breast irradiation using sole interstitial multicatheter brachytherapy versus whole breast irradiation for early breast cancer: 5-year results of a randomised phase III trial – Part I: Local control and survival results

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Purpose/Objective(s): Standard local treatment for patients with early breast cancer is breast-conserving surgery followed by adjuvant whole breast irradiation (WBI). We aimed to assess the effect of accelerated partial breast irradiation (APBI) on local control for patients with stage 0, I and IIA breast cancer who underwent breast-conserving treatment compared with patients who received WBI with boost. In part I we report mature 5-year local control and survival results of a multicenter randomized non-inferiority trial comparing APBI using sole multicatheter brachytherapy to standard WBI.

Materials/Methods: Patients aged ≥40 years with low risk invasive breast cancer and ductal carcinoma in-situ after BCS were randomized to receive either 50 Gy WBI with tumour bed boost of 10 Gy or APBI using multicatheter brachytherapy. The primary endpoint was local recurrence. Secondary endpoints were overall survival, disease-free survival, cumulative incidence of regional recurrence and distant metastasis, incidence and severity of acute and late side effects, cosmesis. The trial is registered with ClinicalTrials.gov, NCT00402519.

Results: Between April 2004 and July 2009, 1184 patients with early stage breast cancer were randomly assigned to receive either WBI or APBI using interstitial multicatheter brachytherapy. Median follow-up of patients was 6.6 years. Baseline factors were evenly distributed across arms. Analysis was done “as treated”. Five-year local recurrence rates were 1.4% (95% CI: 0.5 – 2.4%) in the APBI arm, and 0.9% (95% CI: 0.1 – 1.7%) in the WBI arm (p=0.42). Furthermore second primary ipsilateral breast cancers (different histology compared with the primary tumour) occurred in 1.1% of patients in the WBI group vs 0.9% in the APBI group (p=0.91), difference -0.2% (95% CI: -9.15 – 8.75). 5-year disease-free survival was 95.0% (95% CI: 93.3–96.7%) in the APBI group versus 94.5% (95% CI: 92.5–96.4%) in the WBI group (p=0.8). 5-year overall survival rates were 97.3% (95% CI: 96 - 98.6) in the APBI group vs. 95.6% (95% CI: 93.8 - 97.3) in the WBI group (p=0.1).

Conclusion: Concerning 5-year local control, disease-free survival and overall survival adjuvant APBI using multicatheter brachytherapy after breast conserving surgery for early breast cancer is equally effective with adjuvant WBI with tumour bed boost. This is the first phase III study proving non-inferiority of APBI in comparison to whole breast irradiation for selected early stage breast cancer patients.