BrachyBytes

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New Data Presented at ASTRO 2015 and Published in The Lancet Demonstrate that Accelerated Partial Breast Irradiation (APBI) with Brachytherapy Achieves Favorable Long-Term Efficacy Equivalent to Traditional Whole Breast Irradiation (WBI).

Researchers presenting at ASTRO 2015, the premier radiation oncology scientific event in the world, unveiled new data this week that could fundamentally change the way that early stage breast cancer is treated.

Results from a landmark prospective, randomized, multicenter phase III study conducted in Europe demonstrated that APBI brachytherapy leads to equivalent overall survival and local cancer control rates as compared to WBI after breast conserving surgery for selected patients with early stage breast cancers. These data were presented during the ASTRO official press conference and published in The Lancet, a leading high-impact global peer-reviewed medical journal.

"We have been confidently offering APBI brachytherapy to selected women for years based on numerous phase II, single site and large registry studies that have confirmed the clinical utility of targeted radiation delivered in a condensed timeframe," said Frank A. Vicini, M.D., radiation oncologist, 21st Century Oncology, Royal Oak, Mich. and contributing author to the 2009 and 2013 ASTRO and ABS APBI guidelines. "The results from this landmark, multicenter, prospective randomized clinical trial are the first to offer the critical level one evidence necessary to drive the fundamental changes in breast conserving cancer treatment that patients and healthcare professionals have been awaiting for years."

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The primary objective of the GEC-ESTRO trial was to assess the role of APBI brachytherapy alone compared to whole breast irradiation with boost in a defined group of patients (stage I-IIA) breast cancer or ductal carcinoma in situ (DCIS; stage 0) who underwent breast-conserving surgery.

Researchers evaluated a total of 1,184 patients aged 40 years and above who were randomized to a standardized treatment arm (WBI, n=551) or an investigational treatment arm (APBI, n=633). Median age of enrolled patients was 62 years with nearly half less than 60 years. Patients received follow-up examinations every three months initially and annually after 60 months. The median follow up in the study was 6.6 years.

Study results confirm that adjuvant APBI with brachytherapy after breast conserving surgery is not inferior to adjuvant WBI with boost for selected patients with early breast cancer, with equivalent local recurrence observed with both treatment modalities.

At five-year follow-up, nine patients treated with APBI and five patients treated with WBI had a local recurrence, equating to cumulative recurrence rates of 1.44% and 0.92% (p=0.42) respectively. No significant difference in regional recurrence was observed between groups. The incidence of salvage surgery was low with mastectomy being performed in one APBI patient and zero WBI patients, and lumpectomy being performed in two APBI patients and four WBI patients.

Five-year overall survival was 95.55% with WBI versus 97.27% for APBI, with no observed difference in breast cancer related mortality between treatment arms. Efficacy of APBI at five years was independent of age and tumor characteristics.

Prof. Vratislav Strnad, M.D., Ph.D., chair of the GEC-ESTRO Brachytherapy Working Group and practicing radiation oncologist at University Hospital, Erlangen, Germany stated. "APBI brachytherapy is an attractive treatment approach with a high level of precision, versatility and flexibility. The benefits of APBI brachytherapy include a four-fold reduction in total radiation exposure to healthy surrounding tissue and nearby structures including the chest wall, heart, lungs or skin; preservation of future treatment options; and a notably shorter course of therapy.

A Perspective from Frank Vicini, MD

Frank A. Vicini, M.D., radiation oncologist, 21st Century Oncology, Royal Oak, Mich. and contributing author to the 2009 and 2013 ASTRO and ABS APBI guidelines shares his views on the new data.

Frank Vicini, MD

How might these data potentially impact current clinical practice?

I believe these data have the ability to impact clinical practice. As women learn about the potential advantages of APBI, they will undoubtedly request it. ASTRO announced at the annual meeting a reduction in the age limit for suitable candidates from APBI from 60 to 50 years of age. This is a significant change and the guidelines will go out for commentary this December 2015.

The GEC-ESTRO trial used interstitial multicatheter brachytherapy which is not commonly performed in the United States. Do you expect divergent clinical outcomes with this procedure vs. single entry, strut-based brachytherapy?

In the States, other forms of brachytherapy, such as strut-based, inter-cavity devices are used to deliver radiation. There is no reason to believe that these devices cannot produce the same results as the ones shown in the GEC -ESTRO trial. As long as the radiation is covering the same target area around the tumor bed and delivering that dose safely one should expect the same results as interstitial brachytherapy.

Now that a sizable body of solid clinical evidence exists to support the use of accelerated treatment with brachytherapy, what does the future hold?

I believe we will continue to see shorter periods of radiation treatment for appropriately selected patients. In fact, the GEC-ESTRO data used 7 to 8 fractions (instead of the commonly used 10). A trial known as the "TRI-fraction Radiotherapy Utilized to Minimize Patient Hospital Trips" (TRIUMPH-T) is underway to explore the efficacy of treating patients with radiation delivered over a shortened period of only two to three days. Researchers expect that results from TRIUMPH-T will confirm a similar previous study by the Cancer Institute of New Jersey where researchers showed the approach of giving radiation therapy over a two day period was safe.

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