

New Data Demonstrate Accelerated Partial Breast Irradiation with Multicatheter Brachytherapy is Clinically Equivalent to Whole Breast Irradiation in Treating Early Stage Cancer

- *First large-scale prospective brachytherapy clinical study evaluated 1,184 patients* -
- *Results announced by GEC-ESTRO breast cancer working group at ASTRO 2015* -

SAN ANTONIO – October 19, 2015 – The Groupe Européen de Curiethérapie European Society for Therapeutic Radiology and Oncology (GEC-ESTRO) today announced results from a prospective, randomized, multicenter phase III study comparing accelerated partial breast irradiation (APBI) with interstitial multicatheter brachytherapy to whole breast irradiation (WBI). Results demonstrated that APBI brachytherapy leads to equivalent overall survival, local and regional cancer control rates as compared to WBI after breast conserving surgery for selected patients with early stage breast cancers. The data were presented at the American Society for Radiation Oncology (ASTRO) Annual Meeting, taking place in San Antonio from October 18-21.

“GEC-ESTRO is the most comprehensive clinical study to date evaluating the efficacy of APBI brachytherapy alone versus traditional external whole breast irradiation,” said Prof. Vratislav Strnad, M.D., Ph.D., chair of the GEC-ESTRO Brachytherapy Working Group and radiation oncologist at the Department of Radiation Oncology of University Hospital, Erlangen, Germany. “APBI brachytherapy is an attractive treatment approach with a high level of precision, versatility and flexibility. The benefits of APBI brachytherapy include an at least 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 – four or five days compared to three or up to seven weeks for whole breast irradiation.”

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 with invasive (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.

The multicenter study was conducted at 16 leading medical centers in Austria, the Czech Republic, Germany, Hungary, Poland, Spain and Switzerland.

“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 site-specific 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 study 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 demanding for years.”

About APBI with Brachytherapy

Accelerated partial breast irradiation with brachytherapy (APBI brachytherapy) is a shortened course of high-dose radiation therapy for early-stage breast cancer patients where radiation is delivered directly into the tumor bed. APBI brachytherapy is delivered as part of breast conservation therapy (BCT), which consists of lumpectomy surgery followed by radiation.

The traditional approach for radiation therapy as part of BCT has been whole breast irradiation (WBI). A full course of WBI exposes the entire breast and surrounding critical structures to radiation and requires daily treatments for three to seven weeks where radiation is delivered from outside the breast. APBI brachytherapy, which was developed to address several issues with WBI, delivers radiation only to the lumpectomy cavity and immediate surrounding tissue.

APBI brachytherapy offers three significant advantages over WBI: a reduction in total radiation exposure, particularly to the heart, lungs and skin, the preservation of future treatment options and a reduced treatment time. Since its introduction in the late 1990s, more than 100,000 women in the U.S. have received different types of APBI brachytherapy.

About Cianna Medical, Inc.

Elekta is a human care company pioneering significant innovations and clinical solutions for treating cancer and brain disorders. The company develops sophisticated, state-of-the-art tools and treatment planning systems for radiation therapy, radiosurgery and brachytherapy, as well as workflow enhancing software systems across the spectrum of cancer care. Stretching the boundaries of science and technology, providing intelligent and resource-efficient solutions that offer confidence to both health care providers and patients, Elekta aims to improve, prolong and even save patient lives.

Today, Elekta solutions in oncology and neurosurgery are used in over 6,000 hospitals worldwide. Elekta employs around 3,800 employees globally. The corporate headquarters is located in Stockholm, Sweden, and the company is listed on NASDAQ Stockholm. Website: www.elekta.com.

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