

# BrachyBytes



Less Toxicity. More Patients.  
Now *That's* SAVI.



## Brachytherapy Clinical Evidence Update

New data presented at the ESTRO 35 meeting in Turin, Italy further reinforces treatment as a valid alternative to whole breast irradiation in patients with early breast cancer.

Clinical equivalence of accelerated partial breast irradiation (APBI) and whole breast irradiation (WBI) has already been demonstrated in a multicenter phase III randomized trial:

The Groupe Européen de Curiethérapie European Society for Therapeutic Radiology and Oncology (GEC-ESTRO) trial administered APBI with multicatheter interstitial brachytherapy (published in the Lancet in October 2015).

The primary objective of the GEC-ESTRO trial was to assess the role of APBI brachytherapy alone compared to WBI 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). The median follow up in the study was 6.6 years.

Previously published findings from the study demonstrate that APBI with multicatheter interstitial brachytherapy has an equivalent rate of overall survival, disease-free survival and local and regional cancer

control as compared to traditional WBI with boost after breast conserving surgery for selected patients with stage 0-II breast cancer. At five-year follow-up, cumulative recurrence rates for WBI and APBI were 1.44% and 0.92% (p=0.42) respectively. Five-year overall survival was 95.55% with WBI versus 97.27% for APBI and a low incidence of all serious late side effects (around 3% in both arms) was noted.

***"The convenience of this five-day treatment, coupled with excellent cosmetic outcomes, make this a very attractive treatment option for women with early breast cancer"***

### **Additional insights from the GEC-ESTRO Trial focus on toxicities and cosmesis**

The new data, presented at ESTRO 35 by Prof. Csaba Polgár, MD, PhD, MSc, Professor and Head of the Radiotherapy Center at the National Institute of Oncology in Budapest, Hungary, and co-lead study author, provide additional insights into the late side effect and cosmetic results. Among the 1,184 original study patients, five-year follow-up records on late toxicities and cosmetic results were available for 969 patients (82%).

The five-year toxicity profile was similar for patients treated with brachytherapy or conventional WBI with tumor bed boost. However, a trend towards fewer late skin side effects and better cosmetic results was observed in the APBI arm.

## KEY FINDINGS

The cumulative incidence of grade 2-3 late skin toxicity at five years was 5.7% with WBI vs 3.2% with APBI (p=0.08).

The cumulative risk of grade 2-3 late subcutaneous tissue effects at five years was 6.3% with WBI vs 7.6% with APBI (p=0.53).

The cumulative incidence of severe (grade 3) fibrosis at five years was 0.2% with WBI and 0% with APBI (p=0.46).

The cumulative incidence of grade 2-3 breast pain was low in both the WBI and APBI arms (3.2% vs 1.4% (p=0.04).

The rate of excellent/good cosmetic results judged by patients was 87.2% with WBI vs 90.4% with APBI, and 86.7% with WBI vs 88.2% with APBI (p=0.07) when scored by physicians. However, significantly more patients (43.6% vs 30.9%; p=0.0002) experienced excellent cosmetic results after APBI.

The data from the GEC-ESTRO trial further validates the established and growing body of clinical evidence supporting APBI with multicatheter interstitial brachytherapy as a safe and effective alternative to WBI. According to Prof. Polgár, "The convenience of this five-day treatment, coupled with excellent cosmetic outcomes, make this a very attractive treatment option for women with early breast cancer."



Cianna Medical, Inc., 6 Journey, Suite 125, Aliso Viejo, California 92656  
866.920.9444 • 949.360.0059 • Fax 949.297.4527  
www.ciannamedical.com



**Sign up for our BrachyBytes e-newsletter to read about the latest APBI news!**

©2016 Cianna Medical, Inc. All rights reserved. These products covered by U.S. Patents 7,497,819, 7,497,820, 7,601,113, 7,662,082, 7,736,292, 7,862,496, 7,862,498, 8,398,534, 9,072,893. Other patents pending. BEST Forum is a trademark of Cianna Medical, Inc. SAVI, SCOUT, SAVI Sisters, SAVI SCOUT and Cianna Medical are registered trademarks of Cianna Medical, Inc.