APBI FOR EARLY-STAGE BREAST CANCERS

A STANDARD OF CARE OPTION FOR BREAST CONSERVING THERAPY

• Proven Efficacy
• Excellent Tolerability
• Unparalleled Cosmesis
• Treatment in 2–5 Days

*based on clinicians’ preferred treatment protocol.
Ask us about a 2-day treatment regimen.
“Accelerated Partial Breast Irradiation (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...preservation of future treatment options; and a notably shorter course of therapy.”

Proven Efficacy

GEC-ESTRO Brachytherapy vs. WBI Phase 3 Clinical Trial

No difference in local recurrence, disease-free survival or survival at 5 years

5-year results of accelerated partial breast irradiation using sole interstitial multicatheter brachytherapy versus whole-breast irradiation with boost after breast-conserving surgery for low-risk invasive and in-situ carcinoma of the female breast: a randomized, phase 3, non-inferiority trial.

Vratislav Strnad, MD, Csaba Polgar, MD, et al. – GEC-ESTRO The Lancet, October 2015

Objective: to prove the hypothesis that local control rate is non-inferior with brachytherapy compared to WBI

<table>
<thead>
<tr>
<th>5-Year Results</th>
<th>Brachy</th>
<th>WBI</th>
<th>p-value(^\dagger)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>633</td>
<td>551</td>
<td>–</td>
</tr>
<tr>
<td>Local recurrence</td>
<td>1.4%</td>
<td>0.9%</td>
<td>0.42</td>
</tr>
<tr>
<td>Disease-free survival</td>
<td>95%</td>
<td>94.5%</td>
<td>0.79</td>
</tr>
<tr>
<td>Overall survival</td>
<td>97.3%</td>
<td>95.6%</td>
<td>0.11</td>
</tr>
</tbody>
</table>

“Our results confirm that adjuvant APBI using multicatheter brachytherapy after breast-conserving surgery is as effective as adjuvant whole-breast irradiation for carefully selected patients with early breast cancer.”

\(^\dagger\)Groupe Européen de Curiethérapie of European Society for Radiation And Oncology

\(^\ddagger\)p-value <0.05 indicates statistical significance

Less Toxicity

Favorable Toxicity Rate at 5 Years

<table>
<thead>
<tr>
<th>Toxicity Rate</th>
<th>Yashar, et al ASTRO 2014</th>
<th>Strasser, et al ASTRO 2014(^\ddagger)</th>
<th>Yashar, et al IROBP 2010(^\ddagger)</th>
</tr>
</thead>
<tbody>
<tr>
<td># of Pts/Follow-up</td>
<td>200 pts/56.9 mo.</td>
<td>596 pts/39 mo.</td>
<td>102 pts/22 mo.</td>
</tr>
<tr>
<td>Telangiectasia</td>
<td>1.6%</td>
<td>1.0%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Symptomatic Seroma</td>
<td>3.2%</td>
<td>3.0%</td>
<td>1.9%</td>
</tr>
<tr>
<td>Fat Necrosis</td>
<td>0.5%</td>
<td>0.8%</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

Toxicity rates defined by CTCAE v.3

Preserve Future Treatment Options

“In the case of a tumor recurrence, breast cancer treatment can be performed a second time with APBI brachytherapy allowing the breast to still be preserved and avoiding mastectomy.”

Excellent Cosmetic Results

Limited fibrosis and skin toxicity, providing excellent cosmetic results. Catheter placement can be planned to hide the scar.

APBI Patient Selection Criteria

| Professional Medical Society Consensus Statement: Patient Selection Criteria for Accelerated Partial Breast Irradiation |
|---|---|---|---|
| | ABS | ASBS | ASTRO |
| Age | ≥45 | ≥45 | ≥50 |
| Diagnosis | All invasive subtypes and DCIS | Invasive ductal carcinoma | Invasive ductal/DCIS | Pure DCIS ≤3cm |
| Tumor Size | ≤3cm | ≤3cm | ≤2cm | 2.1–3.0cm |
| Surgical Margins | Negative (Invasive—no tumor on ink; DCIS—≥2mm) | Negative microscopic surgical margins of excision | Negative by at least 2mm | Close (<2mm) |
| Nodal Status | N0 | N0 | N0 (i-, i+) |

Convenient

The short treatment course (five days or less) allows patients to get back to their routines more quickly.
Innovative design of the SAVI Applicator combines the precise dosimetry of interstitial brachytherapy with the ease and convenience of single-entry devices.

Provides targeted radiation where it’s needed most while minimizing dose to healthy tissue—decreases toxicity and lowers the risk of cosmetic side effects.

‘SAVI Sculpt Dosing’ delivers customized radiation based on patient-specific anatomy which may increase the number of women who are eligible for treatment with APBI.

With SAVI, customized catheter sizing helps to increase the number of women who may be eligible for treatment.

The SAVI Prep™ Catheter is a simple, easy to use tool for sizing and selection of the proper SAVI applicator size.

The SAVI Prep 01 Catheter is an option for use in the OR to preserve the cavity and track.

References
2. Cianna Medical press release, New Data Demonstrate Accelerated Partial Breast Irradiation with Multicatheter Brachytherapy is Clinically Equivalent to Whole Breast Irradiation in Treating Early Stage Cancer, October 2015.

Before using refer to Instructions for Use for indications, contraindications, warnings, precautions, and directions for use.

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