**Accelerated Partial Breast Irradiation Using Sole Interstitial Multicatheter Brachytherapy vs Whole Breast Irradiation for Early Breast Cancer: 5-year Results of a Randomized 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 BCS 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 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 DFS 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 OS 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.